United States Government Accountability Office

Report to the Chairman, Subcommittee on Oversight, Committee on Science, Space, and Technology, House of Representatives

September 2014

CHEMICAL ASSESSMENTS

Agencies Coordinate Activities, but Additional Action Could Enhance Efforts

GAO-14-763

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GAO Highlights

Highlights of GAO-14-763, a report to the Chairman, Subcommittee on Oversight, Committee on Science, Space, and Technology, House of Representatives

Why GAO Did This Study

With thousands of chemicals in commercial use in the United States, decision makers rely on toxicity assessment information to examine the risks these substances may pose. Several key federal agencies—including ATSDR, EPA, NIOSH, NTP, and OSHA—as well as state agencies, assess the toxicity of chemicals.

GAO was asked to review chemical toxicity assessment activities. This report (1) describes the chemical toxicity assessment activities selected federal and state agencies undertake; (2) assesses the extent to which these federal agencies' chemical toxicity assessment activities are fragmented, overlapping, or duplicative; and (3) assesses the extent to which these federal and state agencies coordinate their chemical toxicity assessment activities and challenges in doing so. GAO selected five key federal agencies that assess chemicals, and a nonprobability sample of agencies in 10 states that provide a range of assessment activities. GAO reviewed federal agency documentation and compiled summaries of chemical toxicity assessment activities and compared them with one another. GAO interviewed officials from these agencies, representatives from industry, and other stakeholders.

What GAO Recommends

GAO recommends that the Director of OSTP encourage the NSTC to support relevant federal agency officials' efforts to address, as appropriate, the agencies' cross-cutting coordination challenges. OSTP did not provide official written comments, but instead provided technical comments, which GAO incorporated as appropriate.

View GAO-14-763. For more information, contact Steve D. Morris at (202) 512-3841 or morriss@gao.gov.

What GAO Found

The federal agencies GAO reviewed—the Agency for Toxic Substances and Disease Registry (ATSDR), the Environmental Protection Agency (EPA), the National Institute for Occupational Safety and Health (NIOSH), the National Toxicology Program (NTP), and the Occupational Safety and Health Administration (OSHA)—undertake distinct chemical toxicity assessment activities that differ in type and purpose and are driven in part by statutory requirements; the 10 states GAO reviewed largely rely on federal agencies' assessment activities. For example, ATSDR's toxicity assessment activities include evaluating hazards at contaminated sites and NIOSH's activities include identifying potential health risks to workers. Agency officials from all 10 of the selected states told GAO that they have used assessment information produced by these federal agencies in the last 5 years. Officials from 6 of the 10 states told GAO they rely on federal assessments, and the remaining 4 said that they may produce their own assessments in some cases—for example, when a chemical is of interest to the state but is not a national priority.

The chemical toxicity assessment activities at these five federal agencies are fragmented and overlapping, but GAO did not find evidence that these activities are duplicative. Their activities are fragmented because they address the same broad area of national need—providing information on the toxicity of chemicals. The five agencies' activities overlap because some of them have similar goals—such as identifying the extent to which a chemical may cause cancer—or some target similar beneficiaries—such as the general public. GAO did not find evidence of duplication, however, because the agencies did not engage in the same activities or provide the same services to the same beneficiaries. For example, although both NIOSH and EPA develop chemical toxicity assessment information, NIOSH assesses the potential risks that chemicals pose to working-aged adults in occupational settings, such as over the course of a 40-hour workweek, and EPA assesses risks that chemicals pose to a broader population, including children, typically over the course of an entire lifetime.

Officials from all five federal agencies and 3 of the 10 states told GAO that they have coordinated their chemical toxicity assessment activities and also identified challenges. For example, some agency officials identified constraints on sharing confidential business information because of legal restrictions on dissemination of such information across agencies. The Office of Science and Technology Policy's (OSTP) National Science and Technology Council (NSTC) coordinates science and technology policies across the federal government. All executive department and agencies, whether or not they are represented on the NTSC, are to coordinate science and technology policy through it. Given that NSTC has previously facilitated federal coordination on cross-cutting topics, such as nanotechnology and pharmaceuticals in the environment, and given its purpose, an official from OSTP stated that NSTC could serve an interagency coordinating function to address certain cross-cutting challenges. By having an interagency body to address these, and any future cross-cutting challenges, the five selected federal agencies would be positioned to better coordinate their assessment activities in the most effective and efficient manner.

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Abbreviations

ATSDR	Agency for Toxic Substances and Disease Registry
BMC	Benchmark Concentration
BMCL	Benchmark Concentration Confidence Limit
Ca	potential occupational carcinogen
CalEPA	California Environmental Protection Agency
CBI	confidential business information
CERCLA	Comprehensive Environmental Response, Compensation, and Liability Act
EPA	Environmental Protection Agency
FSTRAC	Federal-State Toxicology Risk Analysis Committee
IRIS	Integrated Risk Information System
ITRC	Interstate Technology & Regulatory Council
LOAEL	lowest-observed-adverse-effect level
MOU	memorandum of understanding
MRL	Minimal Risk Level
NCEA	National Center for Environmental Assessment
NIOSH	National Institute for Occupational Safety and Health
NOAEL	no-observed-adverse-effect level
NPL	National Priorities List
NSTC	National Science and Technology Council
NTP	National Toxicology Program
OEHHA	Office of Environmental Health Hazard Assessment
OHAT	Office of Health Assessment and Translation
OSHA	Occupational Safety and Health Administration
OSTP	Office of Science and Technology Policy
PEL	permissible exposure limit
ppm	parts per million
PPRTV	Provisional Peer Reviewed Toxicity Value
REL	recommended exposure limit

RfC	inhalation reference concentration
RoC	Report on Carcinogens
STEL	short-term exposure limit
TCE	trichloroethylene
Tox21	Toxicology in the 21st Century
TSCA	Toxic Substances Control Act
TWA	time-weighted average
UF	uncertainty factor

U.S. GOVERNMENT ACCOUNTABILITY OFFICE
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September 29, 2014

The Honorable Paul Broun
Chairman
Subcommittee on Oversight
Committee on Science, Space, and Technology
House of Representatives

Dear Mr. Chairman:

Thousands of chemicals are in commercial use in the United States, and about 1,000 new chemicals are introduced into commerce each year.[1] These chemicals may provide a wide range of benefits to American consumers, but exposure to certain substances, such as lead or asbestos, may have adverse effects on human health or the environment. Since the 1970s, Congress has enacted various laws to assess and manage risks associated with chemical exposure, and several government agencies have been established to assess and control potential hazards.

Risk assessments—the characterization of the potential adverse health effects of human exposures to environmental hazards—are a key public policy tool for evaluating options for protecting public health and the environment. Chemical risk assessments are a type of risk assessment that examine risks such as the potential for a chemical to cause cancer or the level at which a chemical may cause neurological or developmental effects.[2] Chemical risk assessments typically include four components: (1) hazard identification, (2) dose-response assessment, (3) exposure

[1]Agencies use the term “chemicals” and “substances” synonymously. For the purposes of this report, we will use the term chemicals.

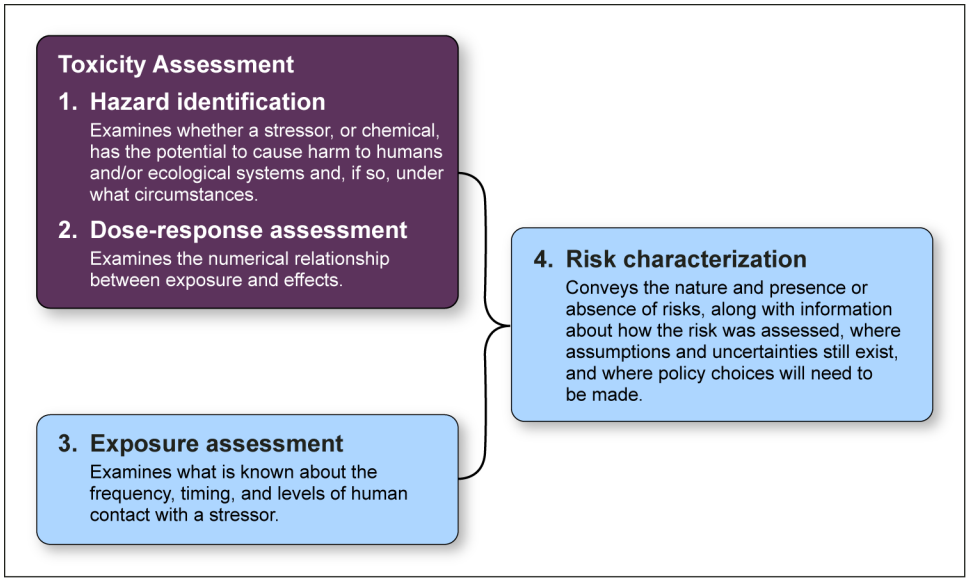
[2]Agencies also assess chemicals’ risk to the environment; however, these assessments are outside the scope of this review.

assessment, and (4) risk characterization.[3] The first two steps—a qualitative hazard identification, and a quantitative dose-response assessment—are commonly referred to together as toxicity assessments.[4] Toxicity values are derived from dose-response assessments. Toxicity assessments weigh available evidence regarding the potential for a chemical to cause adverse effects in exposed individuals and to provide, where possible, an estimate of the relationship between the extent of exposure to a chemical and the increased likelihood and severity of adverse effects. Toxicity assessments combined with information from exposure assessments provide the foundation for characterizing risk (see fig. 1).

[3]These four components are outlined in the 1983 National Academies' National Research Council, *Risk Assessment in the Federal Government: Managing the Process* (commonly known as the Red Book). Hazard identification examines whether a stressor, or chemical, has the potential to cause harm to humans and/or ecological systems, and if so, under what circumstances. Dose-response assessment examines the numerical relationship between exposure and effects. Exposure assessment examines what is known about the frequency, timing, and levels of human contact with a stressor. A risk characterization conveys the risk assessor's judgment as to the nature and presence or absence of risks, along with information about how the risk was assessed, where assumptions and uncertainties still exist, and where policy choices will need to be made.

[4]Toxicity represents the degree to which a chemical is harmful. In this report, the terms toxicity and hazard are used synonymously.

Figure 1: The Four Components of the National Academies' Risk Assessment Process



Source: GAO presentation of the risk assessment component of the National Academies' risk assessment and risk management model used by EPA. | GAO-14-763

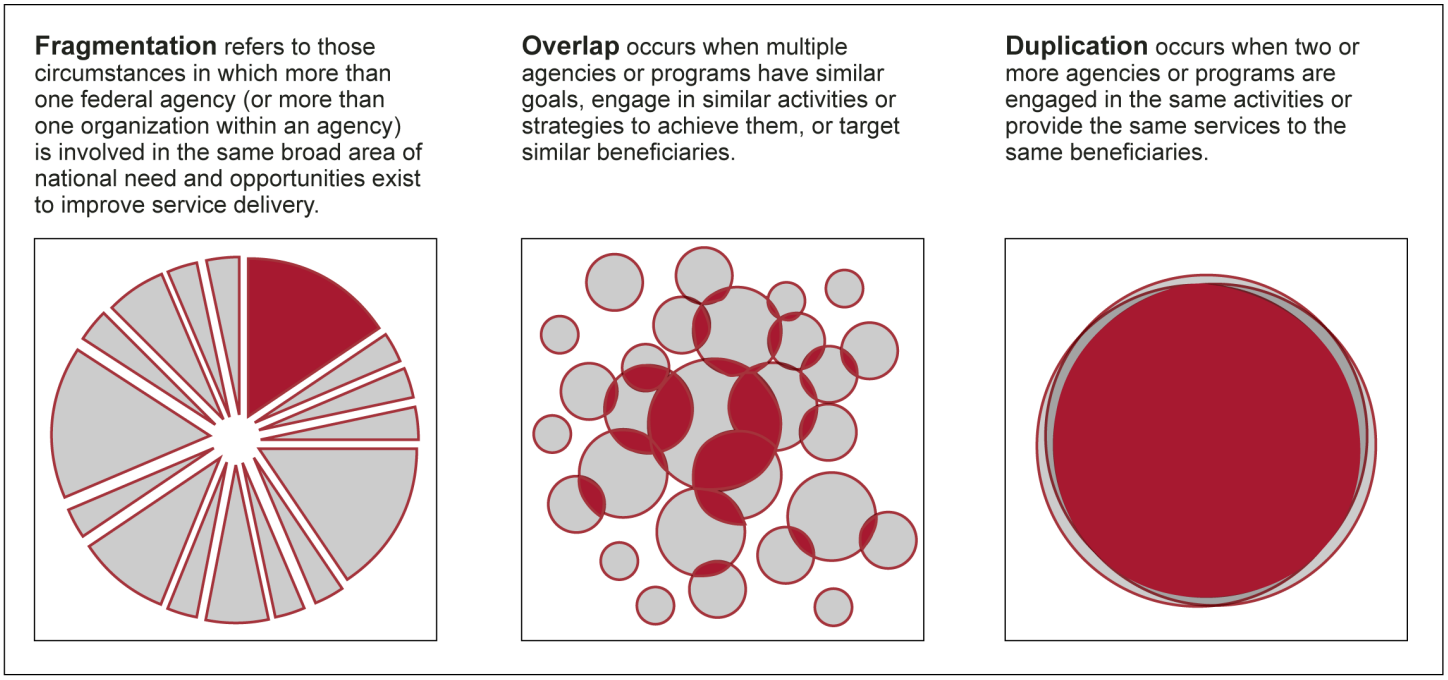
Chemical toxicity assessments are the focus of this report and, while many federal agencies perform chemical toxicity assessments, this report focuses on five agencies that follow this four-step risk assessment process: (1) the Agency for Toxic Substances and Disease Registry (ATSDR); (2) the Environmental Protection Agency (EPA); (3) the Centers for Disease Control and Prevention's National Institute for Occupational Safety and Health (NIOSH); (4) the National Institutes of Health's National Toxicology Program (NTP), within the Department of Health and Human Services; and (5) the Occupational Safety and Health Administration (OSHA), within the Department of Labor.[5] In addition, some state agencies develop their own toxicity assessment information. Information derived from these assessments are used to make decisions on a wide range of criteria, such as emissions standards for sources of

[5]Other federal agencies perform chemical toxicity assessment activities but we limited our review to the key agencies that, as part of their primary mission, perform assessments of chemicals to which there is exposure in the environment, as opposed to exposure from chemicals in or on specific consumer products.

hazardous air pollutants, workplace safety and health standards, and cleanup levels for contaminated sites.

To assess whether there may be opportunities to save federal resources and help agencies provide more efficient and effective services, GAO often evaluates the potential for fragmentation, overlap, or duplication among federal programs. GAO has defined fragmentation, overlap and duplication as shown in figure 2.[6]

Figure 2: GAO's Definitions of Fragmentation, Overlap, and Duplication



Source: GAO. | GAO-14-763

[6]GAO, *Additional Opportunities to Reduce Fragmentation, Overlap, and Duplication and Achieve Other Financial Benefits*, GAO-14-343SP (Washington, D.C.: Apr. 8, 2014). GAO is required to conduct routine investigations to identify programs, agencies, offices, and initiatives with duplicative goals and activities within departments and governmentwide and report annually to Congress in accordance with Section 21 of Pub. L. No. 111-139 (2010).

In 2009, GAO designated the need to transform EPA's process for assessing and controlling toxic chemicals as an area at high risk of waste, fraud, abuse, and mismanagement or in need of broad-based transformation.[7] For example, in March 2008, we reported that data in EPA's Integrated Risk Information System (IRIS)—a human health assessment program that evaluates scientific information on human health effects that may result from exposure to chemicals in the environment—was at serious risk of becoming obsolete because EPA had not been able to keep its existing assessments current or complete assessments of the most important chemicals of concern.[8] In response to our 2008 report and 2009 high-risk designation, EPA revised its IRIS assessment process in May 2009. In December 2011, we reported that these revisions restored EPA's control of the process, increased transparency, and established a 23-month time frame for its less challenging assessments.[9] Progress in other areas, however, has been limited. For example, in our February 2013 update to our high risk list, we found that EPA's initial gains in productivity under the revised process had not been sustained, and that EPA faced both long-standing and new challenges in implementing the IRIS program.[10]

You asked us to provide information on the range of federal chemical toxicity assessment activities. Our objectives for this review are to: (1) describe the chemical toxicity assessment activities selected federal and state agencies undertake; (2) assess the extent to which, if at all, selected federal agencies' chemical toxicity assessment activities are fragmented, overlapping, or duplicative; and (3) assess the extent to which, if at all, selected federal and state agencies coordinate their chemical toxicity assessment activities and the challenges, if any, associated with doing so.

To examine these five federal agencies' chemical toxicity assessment activities, we reviewed publicly available information on these agencies'

[7]GAO, *High-Risk Series: An Update,* GAO-09-271 (Washington, D.C.: Jan. 22, 2009).

[8]GAO, *Chemical Assessments: Low Productivity and New Interagency Review Process Limit the Usefulness and Credibility of EPA's Integrated Risk Information System*, GAO-08-440 (Washington, D.C.: Mar. 7, 2008).

[9]GAO, *Chemical Assessments: Challenges Remain with EPA's Integrated Risk Information System Program,* GAO-12-42 (Washington, D.C.: Dec. 9, 2011).

[10]GAO*, High-Risk Series: An Update,* GAO-13-283 (Washington, D.C.: Feb. 14, 2013).

activities and information from our past reports and compiled summaries of these activities for each agency. We then submitted these summaries to each agency to review for accuracy and incorporated their comments. We also interviewed agency officials as necessary to clarify their comments. We selected a nonprobability sample of 12 state agencies in 10 states that provide a range of chemical assessment activities.[11] We analyzed and reported interview responses using the state as the unit of measure, as opposed to the particular agency. To examine these state agencies' chemical toxicity assessment activities, we conducted structured interviews with officials in these agencies on the scope of their chemical toxicity assessment activities in the last 5 years.

To examine these federal agencies' chemical toxicity assessment activities for fragmentation, overlap, and duplication, we reviewed the summaries of agency toxicity assessment activities and agency documentation that sets forth the scope and purpose of their chemical toxicity assessment activities and compared them with one another and with our definitions of fragmentation, overlap, and duplication. We also further reviewed a nonprobability sample of inhalation toxicity values for 10 selected chemicals as developed by four of the five federal agencies (ATSDR, EPA, NIOSH, and OSHA) and 1 of the 12 selected state agencies, the California Environmental Protection Agency (CalEPA), that conduct toxicity assessment activities for these inhaled chemicals.[12] We selected these 10 chemicals to provide a diverse representation of organic and inorganic chemicals—the two major categories that comprise the universe of all chemicals—with varying structures and chemical

[11]We selected the following 12 state agencies: Alaska Department of Environmental Conservation, the Arizona Department of Health Services, the California Environmental Protection Agency, the Delaware Department of Health and Social Services, the Delaware Department of Natural Resources and Environmental Control, the Minnesota Department of Health, the Minnesota Pollution Control Agency, the Missouri Department of Health & Senior Services, the New Jersey Department of Environmental Protection, the New York Department of Environmental Conservation, the Oklahoma Department of Environmental Quality, and the Texas Commission on Environmental Quality. We interviewed officials from two agencies within Minnesota and Delaware because state officials from these two states indicated that chemical toxicity assessment responsibilities were split among different state agencies, and they recommended that we interview those other agency officials. Because this was a nonprobability sample, the information and perspectives that we obtained from these state agencies are not generalizable to other state agencies.

[12]We did not include NTP among the selected federal agencies because it does not develop quantitative toxicity values and included CalEPA to provide an illustrative example of a state's toxicity values.

properties, which we identified with the assistance of a GAO chemist and a review of chemical toxicity values from federal agencies. We limited our sample to chemicals for which the four of the five selected federal agencies and 1 of the 12 selected state agencies had developed toxicity values. Because this was a nonprobability sample, the information that we obtained on these 10 chemicals is not generalizable to all chemicals.

To examine federal and state agencies' coordination on chemical toxicity assessment activities and any challenges they face, we administered structured interviews to the five selected federal agencies and 12 state agencies. For EPA, which unlike most of the other federal and state agencies has multiple components that conduct chemical toxicity assessments, we also interviewed officials from six program or regional offices to determine the extent to which they coordinate their toxicity assessment activities and identify any challenges to their efforts. In our interviews, we asked officials from each of the five federal agencies whether, and if so, how, their agency had coordinated with each of the other four federal agencies within the past 5 years. The different mechanisms through which agencies coordinate do not necessarily indicate better quality or more effective coordination. Whether the type of coordination mechanism affected quality or effectiveness of interagency coordination is beyond the scope of this review. Agency responses to our structured interviews were further evaluated by considering key practices for collaboration[13] and key considerations for implementing interagency collaborative mechanisms.[14] Appendix I provides additional information on our scope and methodology.

[13]We have previously reported that GAO uses the term "collaboration" broadly to include interagency activities that others have variously defined as "cooperation," "coordination," "integration," or "networking." GAO has done so since there are no commonly accepted definitions for these terms, and we are unable to make definitive distinctions between these different types of interagency activities. Although there is no commonly accepted definition for collaboration, we define it as any joint activity by two or more organizations that is intended to produce more public value than could be produced when the organizations act alone. See GAO, *Results-Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies*, GAO-06-15 (Washington, D.C.: Oct. 21, 2005).

[14]See GAO-06-15; GAO, *Managing for Results: Implementation Approaches Used to Enhance Collaboration in Interagency Groups*, GAO-14-220 (Washington, D.C.: Feb. 14, 2014) and *Managing for Results: Key Considerations for Implementing Interagency Collaborative Mechanisms*, GAO-12-1022 (Washington, D.C.: Sept. 27, 2012).

We conducted this performance audit from May 2013 to September 2014 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Selected Federal Agencies Undertake Distinct Chemical Toxicity Assessment Activities, and Selected States Largely Rely on Federal Assessments

The federal agencies we reviewed undertake distinct chemical toxicity assessment activities that differ in type and purpose and are driven largely by agency needs derived from statutory requirements, while officials in the 10 states we reviewed told us that they largely rely on federal agencies' chemical toxicity assessment activities. Officials in the federal agencies we reviewed told us their toxicity assessments activities include evaluating hazards at contaminated sites, identifying potential health risks to workers, and providing information about potential toxic chemicals to regulators. Officials in 6 of the 10 states we reviewed told us they do not conduct their own toxicity assessments and rely instead on existing sources of information primarily supplied by federal agencies, while officials from the remaining 4 states told us they sometimes produce their own assessments but more often rely on federal sources.

Federal Agencies' Chemical Toxicity Assessment Activities Are Driven by Agency Needs Derived from Statutory Requirements and Differ by Type and Purpose

The toxicity assessment activities that these five federal agencies conducted are driven primarily by agency needs derived from the statutory authorities that created the programs. For example, several programs are designed to provide quantitative values that can be used to regulate chemicals, while others provide a qualitative conclusion about the nature of a chemical that can be shared with regulatory agencies and the public. The scope of some assessments is limited to whether the chemical causes cancer, while other assessments look beyond cancer at neurological, respiratory, and reproductive effects (see fig. 3).

Figure 3: Characteristics of Selected Federal Agencies' Chemical Toxicity Assessment Activities

Characteristics of toxicity assessment activities:	Selected federal agencies:				
	Agency for Toxic Substances and Disease Registry	Environmental Protection Agency	National Institute for Occupational Safety and Health	National Toxicology Program	Occupational Safety and Health Administration
Purpose of toxicity activities:					
To conduct basic research on workplace chemicals			●		
To evaluate Superfund site health hazards	●	●			
To identify potential health risks to workers		●	●		●
To protect public health and the environment		●			
To provide information about potential toxic chemicals to regulators		●	●	●	
Primary statutory authority(ies):					
Clean Air Act		●			
Clean Water Act		●			
Comprehensive Environmental Response, Compensation, and Liability Act	●	●			
Federal Insecticide, Fungicide, and Rodenticide Act		●			
Mine Safety and Health Act			●		
Occupational Safety and Health Act			●		●
Public Health Service Act				●	
Resource Conservation and Recovery Act		●			
Safe Drinking Water Act		●			
Toxic Substances Control Act		●			
Product types issued by agency(ies):					
Integrated Risk Information System (IRIS)		●			
Minimal Risk Level (MRL) contained in a toxicity profile	●				
Office of Health Assessment and Translation (OHAT) Monograph				●	
Permissible exposure limit (PEL) contained in a toxicity assessment					●
Provisional Peer Reviewed Toxicity Values (PPRTV)		●			
Recommended exposure limit (REL)			●		
Report on Carcinogens (ROC)				●	
Qualitative or quantitative assessment:					
Qualitative	●	●	●	●	●
Quantitative	●	●	●		●

● Agency with characteristic cited

Source: GAO. | GAO-14-763

Note: Each of the five selected federal agencies address cancer and non-cancer assessments as part of their toxicity assessment activities.

ATSDR

ATSDR, a federal public health agency of the U.S. Department of Health and Human Services, prepares toxicity assessments—called toxicological profiles—in response to statutory requirements under the Comprehensive Environmental Response, Compensation, and Liability Act (CERCLA). These profiles provide interpretations of data that can be useful for officials evaluating the chemical hazards at hazardous waste sites.[15] During the development of toxicological profiles, if the agency determines that reliable and sufficient data exist to identify the specific health effects that result from exposure to a hazardous substance, the agency will derive Minimal Risk Levels (MRL). MRLs estimate safe levels of human exposure, are quantitative in nature, and are not based on a consideration of cancer effects. To address cancer, the agency issues separate assessments that include qualitative conclusions regarding cancer effects from human exposure to chemicals.

Although ATSDR is not a regulatory agency, CERCLA requires it to prepare a list, in priority order, of chemicals that are most commonly found at hazardous waste sites on the National Priorities List and which are determined to pose the most significant potential threat to human health.[16] ATSDR then must prepare toxicological profiles on substances on that list. ATSDR's toxicological profiles typically evaluate the effects of exposures to hazardous chemicals for three possible durations: acute (14 days or less), intermediate (15-364 days), and chronic (365 days or

[15]See Pub. L. No. 96-510 (1980), *codified as amended at* 42 U.S.C. §§ 9601-9675. CERCLA, also known as Superfund, provides broad federal authority to respond directly to releases or threatened releases of hazardous substances that may endanger public health or the environment.

[16]The National Priorities List (NPL) is the list of national priorities among the known releases or threatened releases of hazardous substances, pollutants, or contaminants throughout the United States and its territories. According to EPA, the NPL is intended primarily to guide EPA in determining which sites warrant further investigation and identifying what cleanup actions might be appropriate. See 42 U.S.C. § 9605(a)(8). Currently, the NPL includes 1,320 sites, and another 51 sites have been proposed.

more).[17] According to ATSDR, these profiles generally take 18 to 24 months to complete. In recent years, ATSDR has typically completed six or seven toxicological profiles each year; a total of 319 new and updated toxicological profiles have been published or are under development.

ATSDR's MRLs are an estimate of daily human exposure to a hazardous substance at or below which that substance will likely not pose a measurable risk of adverse noncancerous effects—such as neurological, respiratory, and reproductive effects—over a specified time period. MRLs are quantitative in nature, and, according to ATSDR's website, are used as screening values to allow ATSDR health assessors and others to identify contaminants at hazardous waste sites and determine whether further investigation is needed to protect communities from exposure. Although MRLs do not consider possible cancer effects, the agency endorses the use of a narrative statement that conveys the agency's qualitative conclusions regarding cancer effects. In this regard, ATSDR adopts the findings for chemicals addressed by the Department of Health and Human Services' most recent biennial Report on Carcinogens, as coordinated by the National Toxicology Program, to the extent available. These are described in ATSDR's Cancer Policy Framework, which defines what the agency has identified as scientifically credible, internally consistent policy positions to guide ATSDR's activities that address the public health implications of exposure to carcinogens.

EPA

EPA toxicity assessments are generally used to determine the levels of chemical pollutants in the air, land, and water that would not present a significant adverse risk to the public and environment. EPA's ability to effectively implement its mission of protecting public health and the environment is critically dependent on credible and timely assessments of the risks posed by chemicals. Such assessments are the cornerstone of scientifically sound environmental decisions, policies, and regulations

[17]CERCLA requires toxicological profiles to include, at a minimum, (a) an examination, summary, and interpretation of available toxicological information and epidemiologic evaluations on a hazardous substance in order to ascertain the levels of significant human exposure for the substance and the associated acute, subacute, and chronic health effects; (b) a determination of whether adequate information on the health effects of each substance is available or in the process of development to determine levels of exposure which present a significant risk to human health of acute, subacute, and chronic health effects; and (c) where appropriate, an identification of toxicological testing needed to identify the types or levels of exposure that may present significant risk of adverse health effects in humans. 42 U.S.C. § 9604(i)(3)(A)-(C).

under a variety of statutes, such as the Toxic Substances Control Act (TSCA),[18] Safe Drinking Water Act,[19] and the Clean Air Act.[20] EPA activities are also authorized by CERCLA, the Resource Conservation and Recovery Act[21], the Clean Water Act, [22] and the Federal Insecticide, Fungicide, and Rodenticide Act.[23] EPA offices provide a variety of toxicity assessments, including both quantitative and qualitative conclusions about cancer and noncancer effects.

According to EPA officials, three EPA program offices and two EPA regional offices develop a variety of chemical toxicity assessments to assist the agency in fulfilling these statutory requirements.[24] These offices include the following:

[18]15 U.S.C § 2601 et. seq. In 1976, Congress passed TSCA to provide EPA with the authority to obtain more information on chemicals and to regulate those chemicals that EPA determines pose unreasonable risks to human health or the environment.

[19]42 U.S.C. § 300f et. seq. Under the Safe Drinking Water Act, EPA is authorized to regulate contaminants in public drinking water systems.

[20]42 U.S.C. § 7401 et. seq. The Clean Air Act is a comprehensive federal law that regulates air pollution from stationary and mobile sources.

[21]42 U.S.C. §§6901 et. seq. (2012). The Resource Conservation and Recovery Act requires, among other things, companies that treat, store, or dispose of hazardous waste to obtain a permit specifying how their facilities will safely manage that waste.

[22]33 U.S.C. § 1251 et. seq. The 1972 Clean Water Act aimed to "restore and maintain the chemical, physical, and biological integrity of the nation's waters."

[23]7 U.S.C § 136 et. seq. The Federal Insecticide, Fungicide, and Rodenticide Act, as amended, generally requires registration of pesticides and authorizes EPA to limit the distribution and sale of unregistered pesticides to the extent necessary to prevent unreasonable adverse effects on the environment.

[24]Although EPA officials indicated that the Office of the Science Advisor does not conduct its own toxicity assessments, EPA officials told us it provides leadership and facilitates the integration of the highest quality science and technology policy into the agency's policies and decisions. According to these officials, the Science Advisor chairs the Science and Technology Policy Council, which may approve actions taken by the agency's Risk Assessment Forum, a standing committee of senior EPA scientists established to promote agency-wide consensus on difficult and controversial risk assessment issues and to ensure that this consensus is incorporated into appropriate agency risk assessment guidance.

- **Office of Research and Development**. The Office of Research and Development produces two types of toxicity assessments,[25] which are developed through its National Center for Environmental Assessment (NCEA). These toxicity assessments provide fundamental information for EPA's risk management decisions, such as whether EPA should establish air emissions standards and water quality standards to protect the public from exposure to particular toxic chemicals. These two types of assessments are as follows:

  - NCEA's IRIS is a human health assessment program that evaluates scientific information on human health effects that may result from exposure to chemicals in the environment.[26] These assessments are used by other EPA offices, as well as federal, state, and local environmental agencies, and some international regulatory bodies. IRIS assessments, which currently include information on about 550 chemicals, undergo extensive internal and external peer review and are developed using a process that allows for public input.[27] According to EPA, the importance of the IRIS Program has increased as its program and regional offices have increasingly relied on IRIS toxicity assessments in making environmental protection and risk management decisions.

  - NCEA's Provisional Peer Reviewed Toxicity Values (PPRTV) provide information to support cleanup decisions at Superfund sites. NCEA prepares PPRTVs for EPA's Office of Solid Waste

[25]ORD also develops Integrated Science Assessments, which are used by EPA's Office of Air and Radiation to develop ambient air quality standards for the Criteria Air Pollutants under the Clean Air Act.

[26]Under its IRIS Program, EPA (1) identifies a chemical's toxicity, or hazardous properties, which are the potential noncancer and cancer human health effects of exposure to a chemical, and (2) assesses the dose-response relationship between exposure to a chemical and the resultant health effects, which describes the magnitude of hazard for potential noncancer effects and increased cancer risk. A human health risk assessment characterizes the nature and magnitude of health risks to humans from exposure to chemical contaminants that may be present in the environment. IRIS toxicity assessments are used along with other information to prepare human health risk assessments. A typical IRIS toxicity assessment contains a qualitative hazard identification and quantitative dose-response assessment.

[27]See, for example, GAO, *Toxic Substances: EPA Has Increased Efforts to Assess and Control Chemicals but Could Strengthen Its Approach*, GAO-13-249 (Washington, D.C.: Mar. 22, 2013).

and Emergency Response when IRIS toxicity assessments are not available. PPRTVs receive internal review by a panel of NCEA scientists and external peer review by independent scientific experts, but they differ from IRIS values in that they do not undergo as extensive a process of internal and external peer review and public participation as IRIS assessments and are generally completed more quickly.

- **Office of Chemical Safety and Pollution Prevention.** Two offices within the Office of Chemical Safety and Pollution Prevention—the Office of Pollution Prevention and Toxics and the Office of Pesticide Programs—also conduct toxicity assessments as follows:

  - The Office of Pollution Prevention and Toxics is responsible for implementing TSCA, which gives EPA the authority to obtain more information on chemicals and to regulate those chemicals that the agency determines pose unreasonable risks to human health or the environment.[28] The office sometimes uses the hazard and dose response information described in an IRIS toxicity assessment for a particular chemical to develop its own subsequent toxicity assessments. We reported in March 2013 that officials from the Office of Pollution Prevention and Toxics told us that IRIS assessments are generally used to estimate risks associated with continuous exposures to a pollutant in the air or water rather than the intermittent exposures that workers and consumers are subject to from chemicals contained in products.[29]

  - The Office of Pesticide Programs, along with state agriculture offices, registers or licenses pesticides for sale and distribution in the United States under the authority of the Federal Insecticide, Fungicide, and Rodenticide Act. States may also have pesticide

[28]See, for example, GAO-13-249.

[29]This use is consistent with the fact that media-specific environmental laws, such as the Clean Air Act and Clean Water Act, are available to limit the concentration of contaminants in water or the ambient air, and TSCA generally requires EPA to defer action to such other laws. However, information on such continuous exposures is still critical for regulation under TSCA. For example, to promulgate a rule under section 6 of TSCA, EPA must establish the effects of a chemical on health and the environment and the magnitude of the exposure of human beings and the environment to such a chemical. See GAO-13-249.

licensing programs. Because pesticides must be registered by EPA, the office reviews scientific information on pesticides submitted by pesticide registrants and comprehensive laboratory-based data on multiple routes of exposure. The office uses this information to conduct comprehensive risk assessments for pesticide active ingredients, among other things.

- **Office of Water.** EPA's Office of Water develops a limited number of toxicity assessments to implement the Clean Water Act and Safe Drinking Water Act. According to Office of Water officials, because the IRIS Program can only select and develop a limited number of IRIS assessments at one time, the Office of Water develops its own assessments for chemicals that have less controversy surrounding them and take less time and staff to complete in order to address some of its programmatic needs.

- **Regional offices.** EPA regional offices, which are responsible for the execution of EPA programs within their respective states and territories; EPA officials told us that two EPA regional offices develop chemical toxicity assessments in support of their work. For example, officials in EPA's Region 2 told us that they rely primarily on IRIS toxicity values. They will also use PPRTVs, values from other federal agencies such as ATSDR, and state toxicity values where available.[30] When officials needed toxicity information for a chemical for which none was available, regional officials worked with others at EPA, NTP, and with officials from a potential responsible party to gather toxicity information that led to the development of a PPRTV for that chemical. Similarly, officials in Region 9 told us that they conducted toxicity assessment activities with ATSDR and NCEA that helped identify a previously unknown effect of a chemical commonly found in waterways throughout the country.[31]

NTP

NTP is an interagency program established in 1978 to coordinate chemical toxicity assessment activities across the Department of Health and Human Services. NTP officials told us the program was created to

[30]Region 2 serves New Jersey, New York, Puerto Rico, the U.S. Virgin Islands, and eight Tribal Nations.

[31]Region 9 serves Arizona, California, Hawaii, and Nevada, as well as a number of Tribal Nations and Pacific Island locations.

coordinate toxicity testing, strengthen the science base in toxicology, develop and validate improved testing methods, and to provide information about potentially toxic chemicals to health-related regulatory and research agencies, scientific and medical communities, and the public. NTP toxicity assessment activities include these four activities. Under the authority of the Public Health Service Act,[32] the NTP is required to produce the biennial Report on Carcinogens (RoC). Although the NTP's primary effort is to conduct toxicological testing on chemicals, it also performs toxicity assessments drawing on both peer reviewed NTP research and testing information and published literature to produce reports, such as its Office of Health Assessment and Translation (OHAT) monographs.[33] In addition, NTP, in coordination with EPA, the Food and Drug Administration, and the National Institutes of Health, is active in the development of the Toxicology in the 21st Century (Tox21) program, which generates data that are to be provided to risk assessors to use when making decisions about protecting human health and environment. These activities include qualitative conclusions about chemical hazards as follows:

- **Report on Carcinogens:** The NTP prepares the RoC in response to a requirement that the Secretary of the Department of Health and Human Services publish a biennial report that contains a list of known or reasonably anticipated carcinogens and information concerning the public's exposure to these substances. The Secretary delegated responsibility for preparing the RoC to the NTP. The RoC identifies and characterizes cancer hazards for the federal government for use by the American people. The RoC is a science-based, public health report that identifies agents, substances, mixtures, or exposures in the environment that may potentially put people in the United States at increased risk for cancer. The RoC contains qualitative information gathered from available sources, including cancer studies on humans, animals and on possible mechanisms of action; potential sources of exposure to humans; and current federal regulations to limit exposures. Substances are listed in the report as either known or reasonably anticipated human carcinogens.

[32]42 U.S.C § 241(b)(4).

[33]NIEHS established OHAT to serve as an environmental health resource to the public and to regulatory and health agencies.

- **OHAT Monographs:** In addition to the RoC toxicity assessments, the NTP issues OHAT Monographs. The OHAT conducts evaluations to assess the evidence that environmental chemicals, physical substances, or mixtures (collectively referred to as "substances") cause adverse health effects and provides opinions on whether these substances may be of concern given what is known about current human exposure levels. The OHAT also organizes workshops or state-of-the-science evaluations to address issues of importance in environmental health sciences.

- **Tox21:** NTP coordinates with several other agencies on another toxicity assessment activity called Tox21.[34] Tox21 pools federal resources and expertise from EPA, NTP, the National Institutes of Health, and the Food and Drug Administration. According to NTP, among the goals of Tox21 are to research, develop, validate, and translate innovative chemical testing methods that characterize toxicity pathways, to prioritize which chemicals need more extensive toxicological evaluation, and to develop models that can be used to more effectively predict how chemicals will affect biological responses.

OSHA

OSHA is an agency within the Department of Labor that conducts chemical toxicity assessments as part of its regulatory responsibilities to promulgate and enforce mandatory occupational safety and health standards. OSHA, created by the Occupational Safety and Health Act of 1970,[35] has the authority to set standards for toxic chemicals, including permissible exposure limits (PEL), which adequately assure to the extent feasible, on the basis of the best available evidence, that no employee will suffer material impairment of health or functional capacity even if the employee has regular exposure during his or her working life.[36] Standards must be reasonably necessary or appropriate, meaning that, before issuing a standard, OSHA must demonstrate that the chemical involved poses a significant risk under workplace conditions permitted by current regulations and that the new limit OSHA promulgates will substantially

[34]NTP's activities for this program–formally called Toxicology Testing in the 21st Century, or Tox21 for short, are in relation to an MOU between EPA, the Food and Drug Administration, the National Institutes of Health, and the NTP.

[35]29 U.S.C. § 651 et. seq.

[36]29 U.S.C. § 655(b)(5).

reduce that risk. Moreover, the standard must be technologically and economically feasible, better able to effectuate the purposes of the OSH Act than any relevant national consensus standards, and use the most cost-effective protective measures.[37] OSHA's analysis includes both qualitative and quantitative components and evaluates the scientific evidence linking exposure to a variety of adverse health effects, including both chronic disease (such as cancer) and effects that may occur over a shorter term.

OSHA health standards are usually directed at reducing the risk of workers developing diseases from occupational exposure to hazardous chemicals. According to OSHA officials, before it issues a health regulation, OSHA reviews the best available evidence pertaining to the adverse health effects of exposure, and evaluates the risk of these effects from exposures allowed under the current standard, as well as the expected impact of the new or revised standard on risk. OSHA officials noted that, because the process of promulgating health standards is resource-intensive and time-consuming, the number of toxicity assessments performed by the agency is limited. Its last two risk assessments conducted as part of its regulatory responsibilities in issuing proposed and final rules were hexavalent chromium, which was proposed in 2004 and finalized in 2006, and crystalline silica, which was proposed in 2013. OSHA noted that another analysis is planned for beryllium.[38]

OSHA's determination of the effects an occupational exposure causes, and which of these effects cause material impairment, is primarily qualitative and relies on evaluation of research conducted by a wide variety of outside organizations, both governmental (such as NIOSH) and nongovernmental. Once OSHA has identified the health effects of

[37]See, e.g., 79 Fed. Reg. 20316, 20561(2104).

[38]According to OSHA data, hexavalent chromium is usually produced by an industrial process and is known to cause cancer. In addition, it targets the respiratory system, kidneys, liver, skin, and eyes. Chromium metal is added to alloy steel and may be used as pigments in dyes, paints, inks, and plastics. It also may be used as an anticorrosive agent added to paints, primers, and other surface coatings. Crystalline silica is a very small particle that is created during work operations involving stone, rock, concrete, brick, block, mortar, and industrial sand that, when inhaled, puts workers at risk for silicosis, lung cancer, chronic obstructive pulmonary disease, and kidney disease. Beryllium is a brittle, steel-gray metal found as a component of coal, oil, certain rock minerals, volcanic dust, and soil. Elemental beryllium is the second lightest of all metals and is used in a wide variety of applications.

concern, the agency conducts an assessment to determine whether long-term exposure at the current PEL would pose a significant risk to workers' health, and whether adoption of a new PEL will substantially reduce this risk. This analysis includes both qualitative and quantitative components. The determination that a particular level of risk is significant is a policy and legal determination, rather than a scientific determination. OSHA also must show, among other things, that a new PEL is technologically and economically feasible.[39]

NIOSH

NIOSH, an Institute of the Centers for Disease Control and Prevention, develops toxicity assessments of workplace chemicals and develops recommended standards for them under the authority of the Occupational Safety and Health Act of 1970.[40] NIOSH develops criteria for a recommended standard, including recommended exposure limits (REL)[41] to describe levels at which no employee will suffer impaired health or functional capacities or diminished life expectancy as a result of his or her work experience.[42] NIOSH publishes chemical assessment information and recommendations for preventing exposure in documents that may contain quantitative or qualitative assessment information on the cancer or noncancer effects of chemicals.

NIOSH officials told us that REL development is a resource-intensive process involving comprehensive review of the scientific literature, statistical modeling that includes sensitivity analyses, and discussion of the health effects of the chemical and the risk assessment process. To date, the NIOSH Pocket Guide to Chemical Hazards lists 677 chemicals or substance groupings, some with NIOSH RELs, 135 of which are carcinogens.[43] In recent years, NIOSH has conducted quantitative risk

[39]These analyses are necessary because the Supreme Court has held that the OSH Act requires that standards be both technologically and economically feasible. *Am. Textile Mfrs. Inst. v. Donovan*, 452 U.S. 490, 513 n.31 (1981).

[40]29 U.S.C. § 651 et. seq. NIOSH also recommends standards to the Mine Safety and Health Administration under the Federal Mine Safety and Health Act of 1977. See 30 U.S.C. § 811(a)(1).

[41]See 29 U.S.C. § 671.

[42]See 29 U.S.C. 669(a)(3).

[43]The NIOSH Pocket Guide to Chemical Hazards is intended as a source of general industrial hygiene information on several hundred chemicals for workers, employers, and occupational health professionals.

assessments as the basis of RELs. NIOSH also recommends appropriate preventive measures to reduce or eliminate the adverse health effects of workplace chemicals of concern. These recommendations are then published for consideration by OSHA for use in promulgating legal standards.[44]

NIOSH assessments are designed to address occupational hazards and risks to workers rather than environmental hazards and risks to the general public. Therefore the most relevant data and results of occupational assessments may differ from those developed to identify environmental hazards and risks to the general public because the population being assessed—workers— does not include young children and has fewer elderly or infirm individuals. NIOSH occupational assessments also consider exposure over a working lifetime—40-hour workweek, 52 weeks per year for 45 years—as opposed to continuous environmental exposure.

NIOSH officials told us they use the best available data as the basis for quantitative risk assessments. These data may be from epidemiological studies, experimental animal studies, and/or mechanistic data in the scientific literature. Because NIOSH has statutory access to workplaces, many NIOSH assessments have also been based on epidemiological investigations of workplace exposures. When NIOSH conducts quantitative assessment using published laboratory animal data for extrapolation to humans, the human equivalent dose associated with an adverse effect is calculated from animal data, and risk is extrapolated to a working lifetime concentration.

Selected States Largely Rely on Federal Chemical Toxicity Assessments

Officials from the 10 selected states that we reviewed generally do not produce their own chemical toxicity assessments; instead, they generally rely on federal chemical toxicity assessments. Officials from 6 of the 10 states we reviewed—Alaska, Arizona, Delaware, Missouri, New York, Oklahoma—told us they have limited resources and relied on chemical toxicity assessments produced by federal agencies. Officials from the remaining 4—California, Minnesota, New Jersey, and Texas—told us they sometimes produce their own chemical toxicity assessment

[44]Unlike OSHA standards, NIOSH recommendations are not binding on employers. E.g., Bergfeld v. Unimin Corp., 226 F.Supp.2d 970, 975 (N.D. Iowa 2002).

information, but they more often rely on federal sources. Officials in all 10 states told us that they have used data in the last 5 years from some or all of the five federal agencies we reviewed.

Officials from California, Minnesota, New Jersey, and Texas told us that although they have the expertise and the resources to produce their own toxicity assessments, they still rely on data from federal agencies. For example, an official from California told us that although the state has the capacity to develop its own toxicity assessments, state officials still regularly consult sources from the five federal agencies we reviewed. Officials from Minnesota told us they evaluate existing sources of toxicity information and sometimes recommend that an existing toxicity standard be used while they evaluate the adequacy of that standard and whether acceptable methods were used in deriving it. They also told us they have the capability to develop hazard identification and dose response analyses that may then be used to evaluate an exposure and set new standards if necessary.

An official from New Jersey told us the state reviews the existing scientific literature for each chemical and, if it determines that the existing toxicity assessments—often provided by a federal agency—meet its needs, it uses them; otherwise, it develops its own. The official told us the state may also develop toxicity assessments for chemicals that are not national priorities, meaning that no federal agency is currently reviewing them. For example, this New Jersey official told us the state developed an assessment for MTBE, a chemical that it indicated was a huge problem for many states and for which IRIS did not have a toxicity value.[45]

An official from Texas told us the state considers several factors in deciding whether to develop its own toxicity values. These factors include whether a toxicity value is available; the age of existing toxicity values; the frequency with which a particular chemical occurs in Texas; whether it disagrees with the scientific judgment used to derive the toxicity value; and public input or concern about a particular chemical.

[45]According to EPA, MTBE was used as a fuel additive in motor gasoline. It is one of a group of chemicals commonly known as “oxygenates” because they raise the oxygen content of gasoline. At room temperature, MTBE is a volatile, flammable and colorless liquid that dissolves rather easily in water.

Selected Federal Agencies' Chemical Toxicity Assessment Activities Are Fragmented and Overlapping but Are Not Duplicative

The chemical toxicity assessment activities at the five federal agencies we reviewed are fragmented because they address the same broad area of national need; they overlap because they have similar goals, and some target similar beneficiaries. We did not find evidence that the activities at these agencies are duplicative because they do not engage in the same activities or provide the same services to the same beneficiaries.

Fragmentation

Selected federal agencies' chemical toxicity assessment activities are fragmented because they each address the same broad area of national need—providing information on the toxicity of chemicals. However, while these federal agencies' all provide information on this same broad area, their activities differ in type and purpose. For example, although both OSHA and EPA develop chemical toxicity assessment information, OSHA provides information on occupational hazards that affect workers, while EPA provides information on environmental hazards that affect the broader population, including children and the elderly. Also, the duration and routes of exposure that are of interest to EPA and OSHA may differ. For example, EPA's IRIS Program assesses the effects of lifetime or chronic exposure to a chemical in the environment, and OSHA assesses the effects of occupational exposure to a chemical in the workplace over a working lifetime, as well as shorter term exposures. For example, EPA's toxicity value for the chemical acrolein differs from OSHA's values because EPA's value is for chronic exposure in the environment, and OSHA's two toxicity values are for 15-minute and 8-hour exposures in the workplace, respectively (see app. II, which contains a table of chemical toxicity values compared across four of the five selected federal agencies and 1 of the 12 selected state agencies). According to OSHA officials, OSHA is primarily concerned with exposure through dermal (skin) contact or inhalation. According to EPA officials, several EPA Offices are concerned with all routes of exposure (dermal, inhalation, and ingestion) for workers and the broader population.

We have previously reported on instances of fragmentation in the federal government. For example, in April 2014,[46] we concluded that

[46]GAO-14-343SP.

fragmentation may result in inefficiencies in how the government delivers services. In March 2011,[47] we also reported that fragmentation has the potential to result in duplication of resources. However, in our April 2014 report, we also found that fragmentation is, by itself, not an indication that unnecessary duplication of efforts or activities exists. For chemical toxicity assessments, we did not find evidence that their activities were duplicative. For example, NTP provides qualitative information to the public on chemicals in the environment known to be or reasonably anticipated to be human carcinogens in its RoC. In contrast, NIOSH provides quantitative and qualitative information to OSHA to support legal standards on both carcinogenic and noncarcinogenic effects of workplace chemicals in its policy documents, which is summarized in the NIOSH Pocket Guide to Chemical Hazards.

In our March 2011 report, we also stated that there can be advantages to having multiple federal agencies involved in a broad area of national need. Agencies can tailor initiatives to suit their specific missions and needs, among other things. For example, OSHA primarily focuses on occupational health issues that affect working-aged adults exposed over an 8-hour workday, and ATSDR is required to focus on environmental health issues that affect the broader population, including children, the elderly, and pregnant women, who may be exposed over longer time periods. In addition, ATSDR has developed three toxicity values for the chemical 1,4-dioxane, a solvent, for nonoccupational environmental exposures (see app. II). These toxicity values differ from OSHA's toxicity value for the same chemical, which is intended only for exposure in the workplace.[48]

Overlap

Selected federal agencies' chemical toxicity assessment activities overlap because some of these activities have similar goals—such as identifying the extent to which a chemical may cause cancer—and because some target similar beneficiaries—such as local health authorities for use in dealing with hazardous waste sites or the general public. However, in

[47]GAO, *Opportunities to Reduce Potential Duplication in Government Programs, Save Tax Dollars, and Enhance Revenue*, GAO-11-318SP (Washington, D.C.: Mar. 1, 2011).

[48]ATSDR developed three toxicity values for 1,4-dioxane at varying exposure durations: (1) acute defined as being 1 to 14 days; (2) intermediate, defined as being 15 to 364 days; and (3) chronic, defined as being greater than 364 days. OSHA's value is for an 8-hour occupational exposure.

March 2011,[49] we concluded that overlapping programs may be aligned in a way that they are complementary. For example, NIOSH toxicity assessments are designed to address occupational hazards and the risks to workers, rather than environmental hazards and the risks to the general public that ATSDR assesses. The population being assessed for occupational risks includes workers who represent a subset of the general public, and it does not include young children and has fewer elderly or infirm individuals. For example, NIOSH developed two toxicity values for the chemical carbon disulfide, a solvent, for workplace exposures, and other agencies, such as ATSDR, developed its toxicity value for environmental exposure that affects the general public (see app. II). NIOSH occupational assessments also consider exposure over a working lifetime—a 40-hour workweek, 52 weeks per year for 45 years—as opposed to continuous environmental exposure.

Selected federal agencies' chemical toxicity assessment activities also overlap in that some of these agencies target similar beneficiaries. For example, both EPA IRIS assessments and ATSDR toxicological profiles are used by a broad audience, including the general public, academics, and international groups. However, beneficiaries for these agencies also differ. EPA's IRIS program provides scientifically supported toxicity values for EPA's program offices and regions for the purpose of making regulatory and risk management decisions, and ATSDR's toxicological profiles target local health authorities for use in dealing with hazardous waste sites. We have previously concluded that overlapping programs or activities can be a harbinger of unnecessary duplication.[50] However, in this case, because these federal agencies develop distinct chemical toxicity assessment information, their activities are largely complementary. For example, as noted previously in this report in figure 3, all five selected federal agencies' activities overlap in that they provide information on both cancer and noncancer effects. However, as previously noted, OSHA provides information on occupational hazards that affect workers, and EPA provides information on the environmental hazards that affect the broader population, including children or the elderly. Further, we have previously concluded that funding research on the same topic may be appropriate and necessary—for example, for

[49]GAO-11-318SP.

[50]GAO-11-318SP.

purposes of replicating or corroborating results.[51] Likewise, officials from two of the five selected federal agencies we reviewed similarly told us that scientific findings are more robust if more than one agency has studied the same chemical and arrived at similar results.

Duplication

We did not find evidence of duplication among selected federal agencies' chemical toxicity assessment activities because the agencies did not engage in the same activities or provide the same services to the same beneficiaries. For example, we did not find duplication between NIOSH and EPA's chemical toxicity assessment activities because NIOSH assesses the potential risks that chemicals pose to working-aged adults in occupational settings (e.g., exposure by dermal contact or inhalation) over the course of working time periods (e.g., an 8- or 10-hour workday or a 40-hour workweek). In contrast, EPA assesses risks that chemicals pose to a broader population as opposed to workers, which includes children and vulnerable populations in the larger nonoccupational environment (e.g., in the air, soil, or groundwater) typically over the course of an entire lifetime.[52] Such differences in the health and age of the people exposed, the environment in which the chemical is present, the routes in which the chemical comes into contact with people, and the length of time people are exposed affect the chemical toxicity information the agencies produce about the levels at which a chemical is safe.

In addition, in reviewing examples of such chemical toxicity information, we analyzed 10 selected chemicals' inhalation toxicity values for four of the five selected federal agencies and 1 of the 12 selected state agencies. We found that these values are not duplicative because they are (1) based on different chemical toxicity assessment activities of differing exposure durations and (2) fulfill distinct programmatic and statutory requirements. For example, EPA and NIOSH developed different toxicity values for the chemical hexavalent chromium,[53] but

[51]GAO-14-343SP.

[52]According to EPA officials, EPA IRIS values typically are concerned with chronic (lifetime) exposures, but EPA Program Offices (e.g., OCSPP, OW, OSWER, and OAR) consider other durations of exposure when assessing risk.

[53]According to EPA's website, hexavalent chromium occurs naturally in the environment from the erosion of natural chromium deposits, and it can also be produced by industrial processes.

EPA's values were for chronic exposure, and NIOSH's value was for a 40-hour per week working lifetime exposure (see app. II). Also, EPA and NIOSH's values each responded to a need from different beneficiaries. Specifically, EPA developed the values in response to stakeholder chemical nominations to the IRIS program,[54] and NIOSH developed the value as part of its responsibilities under the Occupational Safety and Health Act. In addition, as previously noted, both NTP and EPA assess the potential for chemicals to cause cancer and noncancer health effects. According to an NTP official, the agency describes such potential to the public in a qualitative manner based on a targeted population (e.g., pregnant woman), and EPA does so in a qualitative and quantitative manner, consistent with data available for the broader population that includes all subsets (e.g., healthy adults, children, the elderly).

Selected Federal Agencies and States Coordinate Their Chemical Toxicity Assessment Activities and Reported Cross-Cutting Challenges

Officials from all five of the federal agencies and from 3 of the 10 states we reviewed told us that they coordinate their chemical toxicity assessment activities. All of the five federal agencies we reviewed have coordinated with other agencies in the last 5 years, and all the states we reviewed have used federal assessment information, and some have coordinated with federal agencies in the last 5 years. In addition, both officials from selected federal agencies and states identified cross-cutting challenges to this coordination, such as constraints on sharing confidential business information and reliance on informal communication processes.

Selected Federal Agencies and States Coordinate Their Chemical Toxicity Assessment Activities

Officials at all five of the federal agencies and 3 of the 10 states we reviewed told us that, in the last 5 years, they have coordinated their chemical toxicity assessment activities using a variety of coordination mechanisms. We found that all of the federal agencies we reviewed have coordinated with one another, and that states largely rely on federal chemical toxicity assessment information.

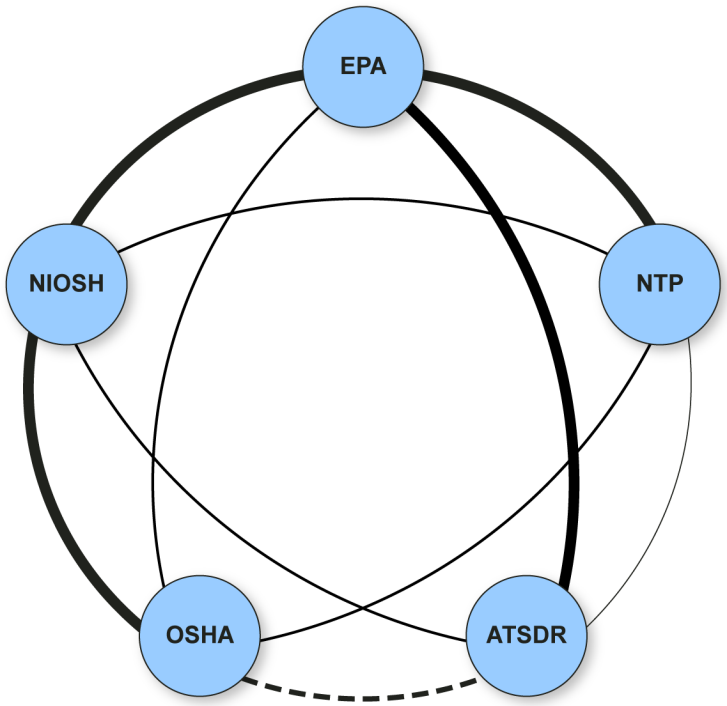
[54]We previously reported in May 2013 that the IRIS Program solicits chemical nominations from stakeholders, such as EPA offices, other federal agencies, and the public. In their nomination forms, stakeholders send EPA the names of chemicals and the reasons for requesting that IRIS toxicity assessments be developed or updated, among other information.

Federal Coordination

Agency officials at the five federal agencies we reviewed told us they have coordinated their chemical toxicity assessment activities in the last 5 years by using four mechanisms: (1) memorandums of understanding (MOU); (2) interagency working groups; (3) data sharing, such as literature search results; and (4) chemical-specific coordination on an as-needed basis, meaning the agencies coordinate in an informal fashion as the need arises for particular chemicals.[55] According to our analysis of structured interviews with selected federal agencies, all five federal agencies have coordinated with at least three other federal agencies using at least three of the four mechanisms (see fig. 4).

[55]The different mechanisms by which agencies coordinate do not necessarily indicate better quality or more effective coordination. Whether the type of coordination mechanism affected quality of effectiveness is beyond the scope of this review. For a discussion of mechanisms for interagency collaboration and definitions, see figure 1 in GAO-12-1022.

Figure 4: Coordination between Selected Federal Agencies on Chemical Toxicity Assessment Activities



Signifies the agency pair coordinates using all four mechanisms:
1. memorandum of understanding
2. interagency working group
3. data sharing, such as literature search results
4. chemical-specific coordination on an as-needed basis

Signifies the agency pair coordinates using the three mechanisms below, but not the memorandum of understanding:
1. interagency working group
2. data sharing, such as literature search results
3. chemical-specific coordination on an as-needed basis

Signifies the agency pair coordinates using the one mechanism below:
1. interagency working group

For example, ATSDR coordinates with NTP, EPA, NIOSH, and OSHA. The coordination between ATSDR and EPA involves the use of all four mechanisms and is indicated by a thick line.

Abbreviations:

ATSDR	Agency for Toxic Substances and Disease Registry
EPA	Environmental Protection Agency
NIOSH	National Institute for Occupational Safety and Health
NTP	National Toxicology Program
OSHA	Occupational Safety and Health Administration

Source: GAO analysis of data obtained from structured interviews with federal officials. | GAO-14-763

Agency officials told us that these interactions have had a positive effect on their chemical toxicity assessment activities. For example:

- ATSDR and EPA coordinate their chemical toxicity assessment activities though an MOU established in 2004 and renewed in 2013. Specifically, ATSDR and EPA's National Center for Environmental Assessment, within its Office of Research and Development, entered into the MOU with a stated purpose of (1) identifying chemical-specific priorities of mutual interest; (2) identifying potential points of interaction that will provide opportunities for collaboration; (3) harmonizing assessment approaches for chemicals of public health concern; (4) increasing the pool of available scientific expertise; and (5) avoiding duplication of effort. Examples of coordination under this MOU include sharing information on chemicals of concern and reviewing and commenting on draft assessments. An EPA official also noted that this MOU enables the agencies to share chemical nomination proposals for their respective programs—ATSDR toxicological profiles and EPA IRIS assessments—and discuss any overlap in chemicals they are assessing.

- OSHA and NIOSH have frequently coordinated on chemical toxicity assessment activities for a number of years by sharing information and data pertaining to emerging occupational safety and health issues; sharing information related to assessment methods, tools, databases and data analysis; and developing and disseminating collaborative and joint-publications in areas of mutual interest. In 2014, OSHA and NIOSH entered into an MOU that formalized these coordination activities and has a stated purpose of advancing the protection of workers, promoting best practices, and encouraging employers to develop and utilize safety and health management programs and effective prevention strategies and technologies.

- NTP coordinates with many federal agencies through its Executive Committee, which is an interagency advisory group that provides programmatic and policy oversight to the NTP Director and meets once or twice a year with high-ranking members from the other four selected federal agencies, as well as other federal agencies. The purpose of the Executive Committee is focused on advising on NTP activities and policies, but NTP officials told us that the Executive Committee has also addressed cross-cutting issues related to chemical toxicity assessments that are beyond a single agency's ability to solve, such as facilitating a forum for ATSDR, NIOSH, and OSHA to present updates of their assessment activities to the other

Executive Committee member agencies; explore interests, needs, and capabilities among member agencies; and identify ways for enhanced cooperation. In another Executive Committee meeting, member agencies discussed efforts within the federal government to adopt the Globally Harmonized System of Classification and Labeling of Chemicals, which includes criteria for the classification of health, physical, and environmental hazards, as well as specifying what information should be included on labels and safety information sheets of hazardous chemicals. NTP officials stated that the agency was interested to hear about agencies' plans for implementation in regulatory programs and how NTP products would be used in the context of the system.

Agencies also provided examples of how they have coordinated through such mechanisms as sharing data and coordinating on specific chemicals on an as-needed basis. For example:

- According to an OSHA official, OSHA shares information informally with EPA and other federal agencies to discuss ongoing research efforts within federal agencies and the current state of science on nanomaterials.[56] Specifically, the OSHA official stated that the agencies are examining the data on specific nanomaterials, such as nanosilver, which, according to EPA, has been incorporated into a variety of consumer products due to their antimicrobial properties, such as some soaps, disinfectant sprays, and children's toys. The OSHA official stated that the agencies are reviewing current scientific data and sharing information on how this type of data can be used by regulatory agencies.

- An ATSDR official stated that ATSDR sometimes refers to EPA's quantitative toxicity assessment information in developing new or

[56]According to an OSHA fact sheet, Nanotechnology is "the understanding and control of matter at the nanoscale, at dimensions between approximately 1 and 100 nanometers (nm)." Nanomaterials can be used in novel applications, such as making stain-free textiles or targeting drugs selectively to cancerous cells. Nanotechnology has the potential to impact many industries, including electronics, healthcare, construction and consumer products. For recent GAO reports on nanotechnology, see GAO, *Nanomanufacturing: Emergence and Implications for U.S. Competitiveness, the Environment, and Human Health*, GAO-14-181SP (Washington, D.C.: Jan. 31, 2014) and GAO, *Nanotechnology: Improved Performance Information Needed for Environmental, Health, and Safety Research*, GAO-12-427 (Washington, D.C.: May 21, 2012).

updating MRLs. For instance, ATSDR is adopting EPA's chronic toxicity values for trichloroethylene (TCE), which is used as a solvent in industrial degreasing operations, and is also used in consumer products such as typewriter correction fluids, paint removers and strippers, adhesives, spot removers, and rug-cleaning fluids. For more information on toxicity values for TCE across selected agencies, please see appendix II.

- An NTP official stated that NTP is working toward sharing data with EPA, such as literature searches on chemicals. The official also stated that, as part of its systematic review process, NTP is developing web-based tools that would allow all federal agencies to extract data from literature, assess the quality of that study, and choose studies for a toxicity assessment in a consistent and structured way. This tool is being funded by EPA, and earlier iterations of these tools have been used in the ongoing EPA assessment of arsenic.

State Use of Federal Chemical Toxicity Assessment Information and Coordination

Officials in the 10 states we reviewed told us that they largely rely on federal agency chemical toxicity assessments. Specifically, officials from agencies in all 10 of the states we reviewed told us they have used chemical toxicity assessment information produced by the federal agencies we reviewed in the last 5 years, even if they had developed their own assessments.[57] Officials from 6 of the 10 states we reviewed—Arizona, California, Delaware, Minnesota, Oklahoma, and Texas—responded that they had used data from all five federal agencies. Officials in the other four states—Missouri, Alaska, New Jersey, and New York—responded that they had used chemical toxicity assessment information from two to four of the five federal agencies (see fig. 5).

[57]Officials from 4 out of the 10 states we reviewed—California, Minnesota, New Jersey, and Texas—responded that their states have developed their own chemical toxicity assessment information in the last 5 years; officials from the remaining 6 out of the 10 states we reviewed—Alaska, Arizona, Delaware, Missouri, New York, and Oklahoma—responded that their states have not developed their own assessment information in the last 5 years and relied exclusively on the federal government for toxicity assessment information.

Figure 5: State-Reported Use of Federal Agency Chemical Toxicity Assessment Information

	Federal agency				
	Agency for Toxic Substances and Disease Registry	Environmental Protection Agency	National Institute for Occupational Safety and health	National Toxicology Program	Occupational Safety and Health Administration
Alaska	●	●		●	
Arizona	●	●	●	●	●
California	●	●	●	●	●
Delaware	●	●	●	●	●
Minnesota	●	●	●	●	●
Missouri	●	●	●		●
New Jersey	●	●		●	
New York	●	●			
Oklahoma	●	●	●	●	●
Texas	●	●	●	●	●

● State agency reported use of federal agency chemical toxicity assessment information

GAO spoke with two agencies within this state and aggregated their responses

Source: GAO analysis of data obtained from structured interviews with state officials. | GAO-14-763

We also asked officials in the 10 selected states we reviewed whether they had coordinated with federal agencies through mechanisms such as MOUs, interagency working groups, data sharing, or chemical-specific coordination on an as-needed basis. Officials in 3 of the 10 states we reviewed—Alaska, Minnesota, and Oklahoma—responded that they have coordinated with three out of the five selected federal agencies in the last 5 years. For example, officials in Minnesota responded that the state has coordinated with ATSDR, EPA, and NTP; officials in Oklahoma responded that the state has coordinated with EPA. An official from the Alaska Department of Environmental Conservation, which does not produce its own chemical toxicity assessments, stated that it coordinated with ATSDR and EPA to assess a chemical contaminating drinking water. The chemical, sulfolane, is an industrial solvent used to separate compounds from chemical mixtures and, according to the Alaska Department, has been the primary solvent used at the North Pole Refinery since 1985. In 2009, then-owner Flint Hills found that sulfolane levels in nearby private drinking water wells were significantly higher than expected, although under the state standard that requires cleanup.

Because there was little toxicity assessment information available on sulfolane, the Alaska Department contacted EPA; at the same time, the state health department contacted ATSDR, resulting in the group of agencies working together to assess the chemical. ATSDR conducted evaluations in 2010 and 2011 that resulted in the establishment of a stricter cleanup standard. After considering ATSDR's research and its own research on previously published data, EPA established a PPRTV for sulfolane in 2012. The state of Alaska set a stricter groundwater cleanup standard based on this PPRTV. The Alaska official we interviewed stated that Alaska lacked the necessary resources to assess sulfolane on its own and working with EPA and ATSDR provided the state with information it needed to move forward on a remediation plan.

Officials from three states we reviewed told us that they coordinated with federal agencies, and officials from all five selected federal agencies told us they coordinated with a variety of state agencies. For example:

- An EPA official stated that its NCEA office operates the Superfund Technical Support Center, which provides assessment technical support and advice to EPA program and regional offices and states on an as-needed basis. The EPA official said that, over the last 5 years, 20 states called the center through a publicly available hotline for information on topics related to chemical risk assessments.

- Officials from ATSDR stated that the agency does not formally coordinate with states, but that states often provide comments during its public comment period on toxicological profiles. Also, ATSDR officials stated that the agency has used state chemical toxicity assessment information to develop its toxicological profiles.

- Officials from OSHA stated that their largest coordination effort with states is through NIOSH's Adult Blood Lead Epidemiology and Surveillance state program, a program funded through NIOSH in which 41 states collect data on levels of blood lead levels. The participating states provide data to NIOSH, which then publishes the data and makes them available in summary form to OSHA. OSHA uses the data to help target workplace inspections and other consultations designed to reduce exposures to lead in the workplace.

Officials from some agencies from selected states responded to our structured interviews that they also coordinate with other states on chemical toxicity assessment activities. Officials from 4 of the 10 selected states—Arizona, Minnesota, Missouri, and New Jersey—told us that they

coordinated with other states. For example, officials from the Minnesota Department of Health told us that it is a member of the Federal-State Toxicology Risk Analysis Committee (FSTRAC), an interagency working group led by EPA's Office of Water that includes other states and whose stated purpose is to foster cooperation, consistency, and an understanding of EPA's and different states' goals and problems in human health risk assessment.

Selected Federal Agencies and States Identified Cross-Cutting Challenges to Coordination

Officials from three of the five selected federal agencies and 2 of the 10 selected states we reviewed identified three cross-cutting challenges to coordination on chemical toxicity assessment activities, including the following:

- **Constraints on sharing confidential business information**. Officials from three offices within EPA we reviewed told us that they are limited in how they can share proprietary information about business practices that chemical companies identify as confidential business information (CBI). Because of legal restrictions on dissemination of CBI, it cannot readily be shared across agencies, which hinders the agencies' coordination of chemical toxicity assessment activities. For example, one official stated that each agency and offices within agencies operate under laws that contain varying provisions relating to CBI, and that these varying provisions complicate their ability to share scientific data and can even make data sharing impossible. This official also stated that these varying provisions hinder their ability to leverage resources. As we concluded in March 2013,[58] when information is claimed as CBI, it limits EPA's ability to share it with other entities, which potentially limits the

[58]GAO-13-249.

effectiveness of these organizations' environmental risk programs.[59] However, TSCA specifies when EPA may publicly disclose chemical information it obtains from chemical companies and provides that chemical companies can claim certain information, such as data disclosing chemical processes, as CBI.[60] We also reported in March 2013 that, according to EPA, 95 percent of information the agency receives on new chemicals contains assertions of confidentiality. EPA officials have stated that they have not had the resources that would be needed to investigate and, as appropriate, challenge such claims.

- **Limited opportunities for agency officials to meet.** According to officials from ATSDR, NIOSH, EPA, and two states, there are few opportunities to meet face-to-face among counterparts from federal and state agencies because budgetary challenges limit their ability to host or attend conferences. For example, one state official noted that

[59]In 2005, we suggested that Congress consider authorizing EPA to share with other entities information chemical companies submit to EPA and identify as CBI, subject to regulations to be established by EPA in consultation with the chemical industry and other interested parties. See GAO, *Chemical Regulation: Options Exist to Improve EPA's Ability to Assess Health Risks and Manage Its Chemical Review Program*, GAO-05-458 (Washington, D.C.: June 13, 2005). We recommended that the EPA Administrator should revise the agency's regulations to require that companies reassert claims of confidentiality submitted to EPA under TSCA within a certain time period after the information is initially claimed as confidential. EPA responded by exploring ways to reduce the number of inappropriate and over-broad claims of confidentiality by companies that submit data to EPA. In March 2013, we found that EPA established new policies in 2011 requiring chemical companies to substantiate claims that information they provide is CBI, which, according to EPA officials, significantly decreased CBI claims for those data. Also in March 2013, we found that EPA does not have a strategy for how the agency will meet the challenge of obtaining the toxicity and exposure data it will need for conducting risk assessments for all 83 chemicals in its work plan under its existing TSCA authority. Specifically, we found that EPA has not broadly sought toxicity and exposure data that companies submit to the European Chemicals Agency or exposure-related data from chemical processors and instead plans to obtain these data, as needed, on a case-by-case basis from chemical companies. However, the agency's strategy does not discuss how EPA would execute these plans or how the data obtained would be used to inform its ongoing or future risk assessment activities, if at all. See GAO-13-249.

[60]The provisions for disclosure of chemical data in section 14 of TSCA specify when EPA may disclose chemical information it obtains under the act. Chemical companies can claim certain information, such as data disclosing chemical processes, as confidential business information. EPA generally must protect confidential business information (CBI) against public disclosure unless necessary to protect against an unreasonable risk of injury to health or the environment. Other federal agencies and federal contractors can obtain access to this CBI in order to carry out their responsibilities. EPA may also disclose certain data from health and safety studies.

in-person conferences were useful because there were opportunities to have spontaneous conversations and establish relationships with their state and federal peers. Due to budget restrictions, however, federal agencies have moved toward hosting webinars instead, which the both federal and state agency officials told us allowed them to share information between state and federal agencies on their assessment activities without the costs associated with traveling, but did not provide the same opportunities for coordination and networking. Officials from one federal agency and one state told us that webinars may preclude the kind of networking that happens at in-person conferences.

- **Informal communication processes**. Officials from NIOSH and three EPA offices told us that they believe that points of contact and communication processes are too informal. For example, one federal agency official stated that there may not be an identified point of contact when individuals retire or leave for another position, which can contribute to loss of continuity and disrupt the transfer of knowledge between agencies if retiring individuals depart without a process for ensuring a smooth transition of knowledge from incumbents to successors. Another federal official stated that an individual in the same position for decades may build relationships with officials in other agencies, but that, without systematic and routine mechanisms to coordinate, it would be challenging for a new individual to identify the right points of contact—particularly at state and regional government agencies. We previously concluded in November 2010 that by using informal coordination mechanisms, agencies may rely on relationships with individual officials to ensure effective collaboration and that these informal relationships could end once personnel move to their next assignments.[61] We also concluded that agencies can strengthen their commitment to work collaboratively by articulating their roles and responsibilities to facilitate decision making in formal documents such as MOUs, interagency guidance, or interagency planning documents.

[61]GAO, *Live Animal Imports: Agencies Need Better Collaboration to Reduce the Risk of Animal-Related Diseases*, GAO-11-9 (Washington, D.C.: Nov. 8, 2010). See also GAO-12-1022.

The National Science and Technology Council Offers an Opportunity to Address Cross-Cutting Challenges

In our September 2012 report that identified mechanisms that facilitate interagency collaboration, we found one mechanism for addressing cross-cutting challenges is through an existing interagency working group.[62] In that report, we concluded that interagency mechanisms or strategies to coordinate programs that address cross-cutting issues may reduce potentially duplicative, overlapping, and fragmented efforts. Officials from four federal agencies told us that one such group that all five selected federal agencies participate in is the National Science and Technology Council (NSTC). NSTC, which was established by Executive Order in 1993, is a council of cabinet-level officials chaired by the President and managed by the Director of the Office of Science and Technology Policy (OSTP).[63] NSTC has multiple committees addressing its broad responsibilities for the scientific and technical work of the executive branch. For example, the NSTC's Committee on Environment, Natural Resources, and Sustainability advises and assists NSTC on federal research and development related to the environment, natural resources, and sustainability. According to the NSTC Executive Order, its principal functions are to coordinate the science and technology policymaking process and ensure science and technology are considered in development and implementation of federal policies and programs, among other things. Further, all executive departments and agencies, whether or not they are represented on the NSTC, are to coordinate science and technology policy through the NSTC and share information on research and development budget requests.

We noted the value of the NSTC in our May 2012 report on a federal interagency program on nanotechnology, in which we stated that the NSTC is the principal means by which the executive branch coordinates science and technology policy.[64] In August 2011, we also reported that one of NSTC's workgroups was involved in another interagency effort to

[62]GAO-12-1022. To identify mechanisms that the federal government uses to lead and implement interagency collaboration, we conducted a literature review of academic work, interviewed a number of experts in governmental collaboration, and analyzed a sample of our prior work. See GAO-12-1022 for additional details on the methodology for identifying these mechanisms.

[63]Congress established OSTP in 1976 to advise the President and others within the Executive Office of the President on considerations of science and technology in federal policy, plans, and programs. OSTP is also charged with leading interagency efforts to develop and implement sound science and technology policies, among other things.

[64]GAO-12-427.

identify and prioritize research needed to better understand pharmaceuticals in the environment and recommend areas of federal collaboration to address those priorities.[65] A July 2014 NSTC report on data from observations of the Earth, such as its land surface and oceans, also illustrates NSTC's involvement in coordinating science activities across agencies. The report was produced as a result of a statutory requirement that OSTP establish a mechanism to ensure greater coordination of research, operations, and activities relating to civilian Earth observation. In response, OSTP convened a task force of 15 federal agencies, and subsequently, the NSTC published the 2014 report. Senior officials from three agencies—ATDSR, EPA, and NIOSH—identified a committee within NSTC as an appropriate forum to address such challenges. An official from OSTP similarly stated that NSTC could serve an interagency coordinating function to address certain cross-cutting challenges, and it has already done so by coordinating chemical toxicity assessment activities and providing opportunities for agency officials to meet in person. By having an interagency body to address the challenges the five selected agencies identified (i.e., constraints on sharing CBI, limited opportunities for agency officials to meet, and informal communication processes) and any future cross-cutting challenges, the five agencies would be positioned to better coordinate their assessment activities in the most effective and efficient manner.

Conclusions

With thousands of chemicals in commercial use in the United States, decision makers rely on information derived from toxicity assessment to examine the risks these substances may pose. Using various mechanisms, the federal agencies and some of the state agencies we reviewed actively coordinate their toxicity assessment activities to avoid unnecessary fragmentation, overlap, and duplication. However, officials in states and federal agencies identified cross-cutting challenges to coordination, such as constraints on sharing information and informal communication processes that hinder agencies' ability to leverage resources, and interfere with officials' ability to work across agency boundaries. By addressing these cross-cutting challenges, state and federal agencies may be positioned to more effectively and efficiently coordinate their chemical toxicity assessment activities.

[65]GAO, *Environmental Health: Action Needed to Sustain Agencies' Collaboration on Pharmaceuticals in Drinking Water*, GAO-11-346 (Washington, D.C.: Aug. 8, 2011).

Recommendation for Executive Action

To improve coordination of federal and state chemical toxicity assessment activities, we recommend that the Director of OSTP encourage the NSTC to support relevant federal agency officials' efforts to address, as appropriate, the agencies' cross-cutting coordination challenges, such as constraints on sharing confidential business information, limited opportunities for agency officials to meet, and informal communication processes.

Agency Comments and Our Evaluation

We requested comments on a draft of this report from the Director, Office of Science and Technology Policy; Secretary of Health and Human Services; Secretary of Labor; and Administrator, Environmental Protection Agency. They did not provide official written comments to include in our report. Instead, they provided technical comments, which we incorporated as appropriate.

As agreed with your office, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the appropriate congressional committees; Director, Office of Science and Technology Policy; Secretary of Health and Human Services; Secretary of Labor; Administrator, Environmental Protection Agency; and other interested parties. In addition, the report will be available at no charge on the GAO website at http://www.gao.gov.

If you or your staff members have any questions about this report, please contact me at (202) 512-3841 or at morriss@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix III.

Steve D. Morris
Acting Director, Natural Resources and Environment Team

Appendix I: Scope and Methodology

To describe the chemical toxicity assessment activities selected federal and state agencies undertake, we examined the chemical toxicity assessment activities of five federal agencies: (1) the Agency for Toxic Substances and Disease Registry (ATSDR), (2) the Environmental Protection Agency (EPA), (3) the National Institute for Occupational Safety and Health (NIOSH), (4) the National Toxicology Program (NTP), and (5) the Occupational Safety and Health Administration (OSHA), which follow the National Academies' four-step risk assessment process. The four steps are (1) hazard identification, (2) dose-response assessment, (3) exposure assessment, and (4) risk characterization.[1] The first two steps—hazard identification and dose-response assessment—are commonly referred to together as toxicity assessments. We reviewed publicly available information on these five federal agencies' assessment activities and information from our past reports, and compiled summaries of these activities for each agency. We then submitted these summaries to each agency to review for accuracy and incorporated their comments as appropriate. We also interviewed agency officials as necessary to clarify their comments. We selected a nonprobability sample of 12 state agencies in 10 states that provide a range of chemical toxicity assessment activities.[2] An official from the Interstate Technology & Regulatory Council (ITRC)—an organization which has expertise in the area of state chemical toxicity assessment activities—reviewed our questions before we interviewed agency officials, and we made changes

[1]Other federal agencies perform chemical toxicity assessment activities, but we limited our review to the key agencies that, as part of their primary mission, perform assessments of chemicals to which there is exposure in the environment, as opposed to exposure from chemicals in or on specific consumer products.

[2]We selected the following 12 state agencies with the assistance of an Interstate Technology & Regulatory Council (ITRC) official, who is knowledgeable in state chemical toxicity assessment activities: the Alaska Department of Environmental Conservation, the Arizona Department of Health Services, the California Environmental Protection Agency, the Delaware Department of Health and Social Services, the Delaware Department of Natural Resources and Environmental Control, the Minnesota Department of Health, the Minnesota Pollution Control Agency, the Missouri Department of Health & Senior Services, the New Jersey Department of Environmental Protection, the New York Department of Environmental Conservation, the Oklahoma Department of Environmental Quality, and the Texas Commission on Environmental Quality.

as appropriate.[3] We asked officials from each state agency to describe the activities their agency performs that might be included in those first two steps of a risk assessment (hazard identification and dose-response), to describe what is within its agency's purview as opposed to the purview of another agency within the same state, and whether it has developed its own chemical toxicity assessment information in the last 5 years. We asked officials from each state agency whether their agency had referred to existing assessment information from each of the five selected federal agencies in the last 5 years, among other entities. Because this was a nonprobability sample, the information and perspectives that we obtained from these state agencies are not generalizable to other state agencies. A contractor entered all agencies' quantitative responses into a single spreadsheet, and their qualitative responses into a single document. We then analyzed responses from our interviews about the extent to which state agencies had developed their own chemical toxicity assessments in the last 5 years, and the extent to which the agencies had used chemical toxicity assessment information from the five federal agencies in the last 5 years.

To assess the extent to which, if at all, selected federal agencies' chemical toxicity assessment activities are fragmented, overlapping, or duplicative, we reviewed the summaries of federal agency assessment activities and federal agency documentation that sets forth the scope and purpose of their assessment activities, and we compared them with one another and with our definitions of fragmentation, overlap, and duplication. We also asked the five federal agencies in our structured interviews whether consolidation—a response to duplication that involves a reduction in either physical infrastructure or management functions—of their agency's chemical toxicity assessment activities with those of the other four federal agencies could improve the federal government's chemical toxicity assessment activities. In addition, we spoke with industry and environmental groups to hear their perspective on the

[3]Established in 1995, ITRC is a state-led, national coalition of personnel from the environmental regulatory agencies of all 50 states and the District of Columbia, three federal agencies, tribes, and public and industry stakeholders. The organization is devoted to reducing barriers to, and speeding interstate deployment of, better, more cost-effective, innovative environmental techniques. ITRC operates as a committee of the Environmental Research Institute of the States, a Section 501(c)(3) public charity that supports the Environmental Council of the States through its educational and research activities aimed at improving the environment in the United States and providing a forum for state environmental policymakers.

chemical toxicity assessment activities of the five federal agencies and state agencies and, the extent to which, if at all, they are duplicative. We also further reviewed a nonprobability sample of inhalation toxicity values for 10 selected chemicals as developed by four of the five federal agencies (ATSDR, EPA, NIOSH, and OSHA) and one state agency, the California Environmental Protection Agency (CalEPA), that conduct toxicity assessment activities for these inhaled chemicals.[4] We illustrated the differences in reported toxicity values in each agency but did not evaluate the validity of these levels or the methods by which they were developed. Because this was a nonprobability sample, the information that we obtained on these 10 chemicals is not generalizable to all chemicals. We did not include NTP among the federal agencies because it does not develop quantitative toxicity values. We included CalEPA to provide an illustrative example of a state's toxicity values. We selected these 10 chemicals to provide a diverse range of organic and inorganic chemicals—the two major categories that comprise the universe of all chemicals—with varying structures and chemical properties, which we identified with the assistance of a GAO chemist and a review of chemical toxicity values from federal agencies. We limited our sample to chemicals for which all of the four of the five selected federal agencies and 1 of the 12 selected state agencies had developed toxicity values.

To examine federal and state agencies' coordination on chemical toxicity assessment activities and any challenges associated in doing so, we administered structured interviews to the five selected federal agencies and 12 state agencies. For EPA, which unlike most of the other federal and state agencies has multiple components that conduct chemical toxicity assessments, we also interviewed officials from six program or regional offices to determine the extent to which they coordinate their toxicity assessment activities and identify any challenges to their efforts.[5] We spoke with officials in two agencies within both Delaware and Minnesota because state officials from these two states indicated that

[4]We selected the following 10 chemicals: (1) acrolein, (2) carbon disulfide, (3) chromium VI (hexavalent chromium), (4) 1,4-dioxane, (5) hydrogen sulfide, (6) manganese, (7) mercury, (8) styrene, (9) toluene, and (10) trichloroethylene (TCE).

[5]We spoke with the following six EPA program and regional offices: (1) Office of Pesticide Programs; (2) Office of Pollution Prevention and Toxics; (3) Office of Research and Development; (4) Office of Water; (5) Region 2, which serves New Jersey, New York, Puerto Rico, U.S. Virgin Islands, and eight Tribal Nations; and (6) Region 9, which serves Arizona, California, Hawaii, Nevada, Pacific Islands, and 148 Tribal Nations.

chemical toxicity assessment responsibilities were split among different agencies within their states. In our interviews, we asked officials from each of the five federal agencies whether their agency had coordinated with each of the other four federal agencies within the past 5 years. For each federal agency that it said it had coordinated with, we asked whether it had used each of five mechanisms: (1) memorandums of understanding (MOU); (2) interagency working groups; (3) data sharing, such as literature search results; (4) chemical-specific coordination on an as-needed basis; and (5) other mechanisms. For each of the mechanisms they said they had used, we asked whether and in what ways the mechanism helped the agency to effectively produce chemical toxicity assessments. For each of the mechanisms they said they did not use, we asked whether they thought that the use of the mechanism would improve the federal government's chemical toxicity assessments. We asked a similar set of questions about each federal agency's coordination with states; we also asked a similar set of questions about each of the 12 selected state agencies' coordination with the five selected federal agencies and other states.[6] We analyzed and reported interview responses using the state as the unit of measure, as opposed to the particular agency. Because we used the state as the unit of measure and not the agency, we reported the response as "yes" for a state in cases where at least one agency official or one agency within Delaware or Minnesota responded "yes." Where applicable, we corroborated coordination activities by obtaining signed MOUs and written interagency agreements. The different mechanisms through which agencies coordinate do not necessarily indicate better quality or more effective coordination. Whether the type of coordination mechanism affected quality of effectiveness is beyond the scope of this review. We combined federal agency responses into an analysis performed by GAO methodologists where we corroborated responses from each agency, and found six discrepancies out of a total of 50 possibilities where an agency

[6]We have previously reported that GAO uses the term "collaboration" broadly to include interagency activities that others have variously defined as "cooperation," "coordination," "integration," or "networking." GAO has done so since there are no commonly accepted definitions for these terms, and we are unable to make definitive distinctions between these different types of interagency activities. Although there is no commonly accepted definition for collaboration, we define it as any joint activity by two or more organizations that is intended to produce more public value than could be produced when the organizations act alone. See GAO, *Results-Oriented Government: Practices That Can Help Enhance and Sustain Collaboration among Federal Agencies*, GAO-06-15 (Washington, D.C.: Oct. 21, 2005).

reported having a mechanism with another agency, but the other agency did not report that mechanism, which we considered reliable for our purposes. In order to increase the reliability of our data, we did not include these six discrepancies. Agency responses to our structured interviews were further evaluated by considering key practices for collaboration and key considerations for implementing interagency collaborative mechanisms.[7]

We conducted this performance audit from May 2013 to September 2014 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[7]See GAO-06-15; GAO-14-220; and GAO-12-1022.

Appendix II: Chemical Inhalation Toxicity Values for Select Agencies

The following tables (tables 1-10) compare inhalation toxicity values for 10 selected chemicals developed by four federal agencies and one state agency: (1) the Agency for Toxic Substances and Disease Registry (ATSDR), (2) the Environmental Protection Agency (EPA), (3) the National Institute for Occupational Safety and Health (NIOSH), (4) the Occupational Safety and Health Administration (OSHA), and (5) California Environmental Protection Agency (CalEPA). Following are explanatory points provided by the agencies that are relevant, as noted, to some or all of the selected chemicals:

- **ATSDR.** To describe any differences in uses between its toxicity values and those of other selected agencies, ATSDR indicated that its Minimal Risk Levels (MRL) are screening levels for environmental exposures; OSHA and NIOSH values are for occupational exposure.

- **CalEPA.** To describe any differences in uses between its toxicity values and those of the other selected agencies, CalEPA reported that its Office of Environmental Health Hazard Assessment (OEHHA) is required to develop guidelines for conducting health risk assessments under the Air Toxics Hot Spots Program. Further, OEHHA developed a Technical Support Document for derivation of reference exposure levels. The latest document addressing the derivation of noncancer reference exposure levels was adopted in December, 2008, and it describes acute, 8-hour, and chronic reference exposure levels. The document presents methodology that explicitly considers possible differential effects on the health of infants, children and other sensitive subpopulations and has been used to develop the reference exposure levels. Two additional Technical Support Documents have been developed, including one for cancer potency factors in May 2009, as well as a revised document for exposure assessment and stochastic analysis in October 2012. The Air Toxics Hot Spots Information and Assessment Act is designed to provide information to state and local agencies and to the general public on the extent of airborne emissions from stationary sources and their potential public health impacts. The act requires that the OEHHA develop risk assessment guidelines for the Air Toxics Hot Spots Program and the most recent guidance manual is available from August 2003. The guidance, intended to address health risks from airborne contaminants released by stationary sources, involves a methodology that is common to other regulatory risk assessment applications, particularly for California programs.

- **EPA.** To describe any differences in uses between its toxicity values and those of other selected agencies, EPA indicated that the agencies' values are developed in response to specific statutory requirements. EPA provided supplementary information about these requirements, as well as the purposes for the values developed by these agencies.

- **NIOSH.** To describe differences in uses between its toxicity values and those of other selected agencies, NIOSH indicated that its recommended exposure limits (REL) are developed for workplace exposures (other agencies develop values for environmental exposure); NIOSH RELs also support OSHA rulemaking.

- **OSHA.** For all chemicals except chromium VI, OSHA described the following differences in uses between its toxicity values and those of other selected agencies, and reasons why it developed its values: for most of its regulated chemicals, OSHA has not relied on an agency risk assessment to establish permissible exposure limits (PELs). Rather, these PELs were adopted shortly after formation of the agency in 1971 from approximately 400 occupational exposure limits that were based on the American Conference of Governmental Industrial Hygienist's 1968 list of Threshold Value Limits. On January 19, 1989, OSHA published a final rule on air contaminants that lowered 212 of OSHA's existing PELs for toxic substances and set PELs for 164 toxic substances that had been previously unregulated. In doing so, OSHA relied heavily on the already published and widely accepted Threshold Limit Values published by the American Conference of Governmental Industrial Hygienists and the RELs developed by NIOSH. In 1992, a federal appellate court vacated these standards, holding that OSHA had failed to establish that the new standards were technologically and economically feasible.[1] As a result, OSHA resumed enforcing, and employers were required to comply with, the air contaminant exposure limits that were in effect prior to the issuance of the new limits on January 19, 1989. In reinstating the previous limits, OSHA said that it continued to believe that many these old limits were out of date (they predate 1968) and not sufficiently protective of employee health based on current

[1]American Federation of Labor and Congress of Industrial Organizations v. Occupational Safety and Health Administration, 965 F.2d 962 (11th Cir. 1992).

scientific information and expert recommendations. In addition, OSHA observed that many of the substances for which OSHA had no PELs presented serious health hazards to employees. In commenting on the information in this appendix, OSHA officials stated that they continue to believe the limits contained in the 1989 rulemaking reduced significant risks of material impairment of health or functional capacity, and were technologically and economically feasible.

GAO note: the agencies listed below have developed toxicity values that vary in exposure. Specific terms included are “acute,” which ATSDR defines as exposure of between 1 and 14 days, and which CalEPA defines as exposure of 1 hour. ATSDR defines “intermediate” exposure is being between 15 and 364 days. Both CalEPA and EPA define “chronic” exposure as being over the course of a lifetime, and ATSDR defines “chronic” as being exposure of 365 days or longer. NIOSH and OSHA develop toxicity values that with exposure levels that vary between exposure durations of 15 minutes, 8 hours, 10 hours, or a 40-hour week for a 45-year working lifetime. In addition, some agencies may use safety or uncertainty factors that protect susceptible populations. These factors may result in values that cannot be compared.

Table 1: Acrolein

	ATSDR	CalEPA	EPA	NIOSH	OSHA
Assessment date	2007	2008	2003	1988	1989
Number of reference values developed	2	3	1	2	2
First reference value (mg/m^3)	0.007 mg/m^3 (Acute: 1-14 days)	0.0025 mg/m^3 (Acute)	0.00002 mg/m^3 (Chronic)	0.25 mg/m^3 (10-hour TWA, 40-hours a week for a working lifetime)	0.25 mg/m^3 (8-hour TWA)
Second reference value (mg/m^3)	0.00009 mg/m^3 (Intermediate 15-364 days)	0.00035 mg/m^3 (Chronic)	-	0.8 mg/m^3 (15-minute TWA STEL)	0.8 mg/m^3 (15-minute STEL)
Third reference value (mg/m^3)	-	0.0007 mg/m^3 (8-hour, general population)	-	-	-
Any differences in the values' uses	ATSDR's acute and intermediate MRLs for Acrolein are for up to 14 day exposure and 15-364 day exposure, respectively; CalEPA acute values are for 1-hour and 8-hour exposures. See introductory text.	See introductory text.	See introductory text.	NIOSH contributed to the OSHA assessment for acrolein as part of the 1988 OSHA PEL Update effort. NIOSH adopted the values as RELs.[a] See introductory text.	See introductory text.

Legend:

ppm parts per million

STEL short-term exposure limit

Sources: Federal and state agency data. | GAO-14-763.

[a]The OSHA PEL for acrolein is 0.1 ppm (0.25 mg/m^3). This value was not changed in the1989 PEL Update final rule. The 0.3 ppm STEL was added in the PEL Update final rule, but was vacated by the 1992 court decision (see introductory text). Therefore, OSHA has the PEL but not a STEL for acrolein. NIOSH kept the limits developed in the 1988 effort.

Table 2: Carbon Disulfide

	ATSDR	CalEPA	EPA	NIOSH	OSHA
Assessment date	1996	1999 (acute), 2002 (chronic)	1995	1988	1989
Number of reference values developed	1	2	1	2	2
First reference value (mg/m^3)	0.9 mg/m^3 (Chronic: 365 days and longer)	6.2 mg/m^3 (Acute)	0.7 mg/m^3 (Chronic)	3 mg/m^3 (10-hour TWA, 40-hours a week for a working lifetime)	12 mg/m^3 (8-hour TWA)
Second reference value (mg/m^3)	-	0.8 mg/m^3 (Chronic)	-	30 mg/m^3 (15-minute TWA STEL)	36 mg/m^3 (STEL)
Any differences in the values' uses, additional notes	EPA used benchmark concentration for a point of departure of 6.3 ppm vs ATSDR LOAEL of 7.6 ppm; ATSDR used LOAEL of 7.6 and UF=30. See introductory text.	See introductory text.	See introductory text.	NIOSH contributed to the OSHA assessment for carbon disulfide as part of the 1988 OSHA PEL Update effort. NIOSH had assessed carbon disulfide in a 1977 criteria document, and these limits were proposed in the 1988 PEL Update final rule. However, OSHA promulgated slightly higher limits because of feasibility concerns.[a] See introductory text.	See introductory text.

Legend:

LOAEL lowest-observed-adverse-effect level

UF uncertainty factor

Sources: Federal and state agency data. | GAO-14-763.

[a]The OSHA PEL is 20 ppm, 30 ppm ceiling and a 100 ppm 30-minute maximum peak. The 1989 PEL Update final rule established a 4 ppm TWA and 12 ppm STEL, plus a skin designation, but were vacated by the 1992 court decision (see introductory text). NIOSH kept the proposed limits developed in the 1988 effort of 1 ppm TWA and 10 ppm STEL.

Table 3: Chromium VI (Hexavalent Chromium)

	ATSDR	CalEPA	EPA	NIOSH	OSHA
Assessment date	2012	2001	1998	2013	2006
Number of reference values developed	3	1	2	1	1
First reference value (mg/m^3)	0.000005 mg/m^3 (aerosol mists) (Intermediate 15-364 days)	0.0002 mg/m^3 (except chromic trioxide) (Chronic)	0.000008 mg/m^3 (Chromic acid mists) (Chronic)	0.0002 mg/m^3 (8-hour TWA, 40-hours a week for a working lifetime)	0.00025 mg/m^3 (1×10^{-3} Risk Specific Exposure Level over 45-year working life)
Second reference value (mg/m^3)	0.000005 mg/m^3 (aerosol mists) (Chronic > 364 days)	-	0.0001 mg/m^3 (particulates) (Chronic)	-	-
Third reference value (mg/m^3)	0.0003 mg/m^3 (Particulates) (Intermediate 15-364 days)	-	-	-	-
Any differences in the values' uses, additional notes	EPA used a UF=90, ATSDR used a UF=100. CalEPA applied a UF=300. See introductory text.	See introductory text.	See introductory text.	NIOSH develops Criteria Documents to synthesize and assess the health data supporting recommendations for controlling workplace exposures to hazardous substances, as directed in the Occupational Safety and Health Act.[a] See introductory text.	See introductory text.

Source:s Federal and state agency data. | GAO-14-763.

[a]NIOSH states that in 2013, NIOSH published Criteria for a Recommended Standard: Occupational Exposure to Hexavalent Chromium. This document presented the health basis for NIOSH's workplace recommendations and provides guidance for employers desiring to protect workers beyond what is required in the OSHA standard. Besides health effects, OSHA also considered, among other things, technological and economic feasibility when promulgating the Hexavalent Chromium Standard in 2006. The 2006 final rule establishes an 8-hour TWA exposure limit of 5 micrograms per cubic meter of air (5 $\mu g/m^3$). This is a reduction from the previous PEL of 52 $\mu g/m^3$. For chromium VI, OSHA indicated that the Risk Specific Exposure Level was the 8-hour, time-weighted average (TWA) projected to result in an excess lifetime cancer risk range of 5.2×10^{-4} to 2.3×10^{-3} over a 45-year working lifetime (i.e., ages 20 to 65). The estimate is based on a quantitative risk assessment used to support the OSHA 2006 occupational standard, which was developed pursuant to the requirements of the OSH Act. According to OSHA officials, the Risk Specific Exposure Level is not the enforceable OSHA PEL; the OSHA PEL was set at 5 $\mu g/m^3$, a level that was technologically and economically feasible in most Cr(VI) operations, most of the time. GAO note: OSHA issued the standard for chromium VI in February 2006. The 2006 final rule establishes an 8-hour TWA exposure limit of 5 micrograms per cubic meter of air (5 $\mu g/m^3$), a reduction from the previous PEL of 52 $\mu g/m^3$.

Table 4: 1,4-Dioxane

	ATSDR	CalEPA	EPA	NIOSH	OSHA
Assessment date	2012	2008 (acute), 2000 (chronic)	2013	1988	1989
Number of reference values developed	3	2	1	2	1
First reference value (mg/m^3)	7.2 mg/m^3 (Acute: 1-14 days)	3 mg/m^3 (Acute)	0.03 mg/m^3 (Chronic)	Ca: "as low as feasible" (10-hour TWA, 40-hours a week for a working lifetime)	90 mg/m^3 (8-hour TWA)
Second reference value (mg/m^3)	0.72 mg/m^3 (Intermediate 15-364 days)	3 mg/m^3 (Chronic)	-	3.6 mg/m^3 (30-minute TWA ceiling value)	-
Third reference value (mg/m^3)	0.11 mg/m^3 (Chronic > 364 days)	-	-	-	-
Any differences in the values' uses, additional notes.	EPA added an additional UF=3 for database deficiency; ATSDR's acute and intermediate MRLs are for up to 14-day exposure and 15-364 day exposure, respectively; CalEPA acute values are for 1-hour and 8-hour exposures. ATSDR used a more recent 2009 study, Cal EPA used a 1974 study. See introductory text.	See introductory text.	See introductory text.	NIOSH contributed to the OSHA assessment for dioxane as part of the 1988 OSHA PEL Update effort. NIOSH had assessed dioxane in a 1977 criteria document and in 1988 continued to recommend a ceiling limit of 1 ppm and a (Ca) notation. OSHA adopted a 25 ppm PEL plus a skin notation in the 1988 PEL Update effort.[a] See introductory text.	See introductory text.

Legend:

Ca potential occupational carcinogen

Sources: Federal and state agency data. | GAO-14-763.

[a]The OSHA PEL for dioxane is 100 ppm (360 mg/m^3) with a skin designation. These values were changed to 25 ppm plus a skin designation in the 1989 PEL Update final rule, but were later vacated by the 1992 court decision (see introductory text). NIOSH kept the REL it developed in the 1988 effort.

Table 5: Hydrogen Sulfide

	ATSDR	CalEPA	EPA	NIOSH	OSHA
Assessment date	2006	2008 (acute), 2000 (chronic)	2003	1988	1989
Number of reference values developed	2	2	1	1	2
First reference value (mg/m^3)	0.1 mg/m^3 (Acute: 1-14 days)	0.042 mg/m^3 (Acute)	0.002 mg/m^3 (Chronic)	15 mg/m^3 (10-minute TWA ceiling value)	15 mg/m^3 (8-hour TWA)
Second reference value (mg/m^3)	0.03 mg/m^3 (Intermediate 15-364 days)	0.01 mg/m^3 (Chronic)	-	-	21 mg/m^3 (15-minute STEL)
If aware of other values, any differences in the values' uses	EPA RfC used the same study as ATSDR intermediate MRL with additional UF for duration extrapolation. CalEPA chronic REL also used a subchronic study with additional UF for duration extrapolation. ATSDR acute MRL is for 1-14 days exposure; CalEPA acute REL is for 1-hour exposure. See introductory text.	See introductory text.	See introductory text.	NIOSH contributed to the OSHA assessment for hydrogen sulfide as part of the 1988 OSHA PEL Update effort. NIOSH had assessed hydrogen sulfide in a 1977 criteria document and the ceiling limit was recommended to OSHA in the 1988 PEL Update effort. OSHA chose limits of 10 ppm as an 8-hour TWA and 15 ppm as a STEL.[a] See introductory text.	See introductory text.

Legend:

RfC inhalation reference concentration

Sources: Federal and state agency data. | GAO-14-763.

[a]The OSHA PEL for hydrogen sulfide is 20 ppm with a 50 ppm maximum peak (10-minute TWA). The exposure limits in the 1989 PEL Update final rule (10 ppm 8-hour TWA and 15 ppm STEL) were vacated by the 1992 court decision (see introductory text). NIOSH kept the limits it developed in the 1988 effort.

Table 6: Manganese

	ATSDR	CalEPA	EPA	NIOSH	OSHA
Assessment date	2012	2008	1993	1988	1989
Number of reference values developed	1	2	1	2	2
First reference value (mg/m^3)	0.0003 mg respirable manganese/m^3 (Chronic: 365 days and longer)	0.00017 mg/m^3 (8-hour, general population)	0.00005 mg/m^3 (Chronic)	1 mg/m^3 (10-hour TWA, 40-hours a week for a working lifetime)	1 mg/m^3 (8-hour TWA)
Second reference value (mg/m^3)	-	0.00009 mg/m^3 (Chronic)	-	3 mg/m^3 (15-minute TWA STEL)	3 mg/m^3 (15-minute STEL)
Any differences in the values' uses, additional notes	ATSDR chronic MRL used BMC10, EPA chronic RfC used LOAEL, CalEPA chronic REL used BMCL05, all three based on Roels et al. 1992. See introductory text.	See introductory text.	See introductory text.	NIOSH contributed to the OSHA assessment for manganese as part of the 1988 OSHA PEL Update effort.[a] See introductory text.	See introductory text.

Legend:

BMC Benchmark Concentration

BMCL Benchmark Concentration Confidence Limit

Sources: Federal and state agency data. | GAO-14-763.

[a]The OSHA PEL for manganese is a ceiling value of 5 mg/m^3. This was changed in the 1989 PEL Update final rule to an 8-hour TWA of 1 mg/m^3 and a STEL of 3 mg/m^3, but were vacated by the 1992 court decision (see introductory text). NIOSH kept the limits developed in the 1988 effort.

Table 7: Mercury

	ATSDR	CalEPA	EPA	NIOSH	OSHA
Assessment date	1999	2008	1995	1988	1989
Number of reference values developed	1	3	1	1	4
First reference value (mg/m^3)	0.0002 mg/m^3 Chronic: 365 days and longer)	0.0006 mg/m^3 (Acute)	0.0003 mg/m^3 (Chronic)	0.05 mg/m^3 (10-hour TWA, 40-hours a week for a working lifetime)	0.005 mg/m^3 (vapor) (8-hour TWA)
Second reference value (mg/m^3)	-	0.00006 mg/m^3 (8-hour, general population)	-	-	0.01 mg/m^3 (organo) (8-hour TWA)
Third reference value (mg/m^3)	-	0.00003 mg/m^3 (Chronic)	-	-	0.03 mg/m^3 (organo) (15-minute STEL)
Fourth reference value (mg/m^3)	-	-	-	-	0.01 mg/m^3 (aryl and inorganic) (Ceiling - not to exceed at any time)
Any differences in the values' uses, additional notes	EPA used UF=30; CalEPA used UF=300; ATSDR used UF=30. EPA and CalEPA used multiple studies to identify a LOAEL of 0.025 vs ATSDR using 0.026 from Fawer et al. EPA and CalEPA adjusted for ventilation rates. See introductory text.	See introductory text.	See introductory text.	NIOSH contributed to the OSHA assessment for mercury as part of the 1988 OSHA PEL Update effort. NIOSH had assessed mercury in a 1973 criteria document and the REL of 0.05 mg/m^3 was proposed to OSHA as part of that process.[a] See introductory text.	See introductory text.

Sources: Federal and state agency data. | GAO-14-763.

[a]The OSHA PEL for mercury is a ceiling value of 0.1 mg/m^3. This was changed in the 1989 PEL Update final rule to an 8-hour TWA of 0.05 mg/m^3, but was vacated by the 1992 court decision (see introductory text). NIOSH kept the limits developed in the 1988 effort.

Table 8: Styrene

	ATSDR	CalEPA	EPA	NIOSH	OSHA
Assessment date	2010	2008 (acute), 2000 (chronic)	1992	1988	1989
Number of reference values developed	2	2	1	2	2
First reference value (mg/m^3)	21 mg/m^3 (Acute: 1-14 days)	21 mg/m^3 (Acute)	1 mg/m^3 (Chronic)	215 mg/m^3 (10-hour TWA, 40-hours a week for a working lifetime)	215 mg/m^3 (8-hour TWA)
Second reference value (mg/m^3)	0.84 mg/m^3 (Chronic: 365 days or longer)	0.9 mg/m^3 (Chronic)	-	425 mg/m^3 (15-minute TWA STEL)	425 mg/m^3 (15-minute STEL)
Any differences in the values' uses, additional notes	Chronic inhalation MRL used a more recent study (Benignus et al 2005). Acute MRL is for 1-14 days exposure, CalEPA acute REL is for 1-hour exposure. See introductory text.	See introductory text.	See introductory text.	NIOSH contributed to the OSHA assessment for styrene as part of the 1988 OSHA PEL Update effort. NIOSH had assessed styrene in a 1983 criteria document and the REL of 50 ppm/STEL of 100 ppm was recommended to OSHA in the PEL Update final rule. OSHA agreed.[a] See introductory text.	See introductory text.

Sources: Federal and state agency data. | GAO-14-763.

[a]The OSHA PEL for styrene is 100 ppm as an 8-hour TWA with a ceiling limit of 200 ppm with a 600 ppm 5-minute maximum peak in any 3-hours. This was changed in the 1989 PEL Update final rule to a 50 ppm 8-hour TWA and 100 ppm 15-minute STEL, but were vacated by the 1992 court decision (see introductory text). NIOSH kept the limits developed in the 1988 effort.

Table 9: Toluene

	ATSDR	CalEPA	EPA	NIOSH	OSHA
Assessment date	2000	2008 (acute) 2000 (chronic)	2005	1988	1989
Number of reference values developed	2	2	1	2	2
First reference value (mg/m^3)	3.8 mg/m^3 (Acute: 1-14 days)	37 mg/m^3 (Acute)	5 mg/m^3 (Chronic)	375 mg/m^3 (8-hour TWA, 40-hours a week for a working lifetime)	375 mg/m^3 (8-hour TWA)
Second reference value (mg/m^3)	0.3 mg/m^3 (Chronic: 365 days and longer)	0.3 mg/m^3 (Chronic)	-	560 mg/m^3 (15-minute TWA STEL)	560 mg/m^3 (15-minute STEL)
Any differences in the values' uses, additional notes	EPA's RfC is based on an arithmetic mean of NOAEL values from 10 different studies that was chosen to represent an average point of departure. See introductory text.	See introductory text.	See introductory text.	NIOSH contributed to the OSHA assessment for toluene as part of the 1988 OSHA PEL Update effort. NIOSH had assessed toluene in a 1973 criteria document but the reassessment lowered the REL. OSHA adopted the 100 ppm PEL in the PEL Update final rule.[a] See introductory text.	See introductory text.

Legend:

NOAEL No-observed-adverse-effect level

Sources: Federal and state agency data. | GAO-14-763.

[a]The OSHA PEL for toluene is 200 ppm as an 8-hour TWA with a ceiling limit of 300 ppm and a 10-minute maximum peak of 500 ppm. This was changed in the 1989 PEL Update final rule to a 100 ppm 8-hour TWA and a 150 ppm STEL, but were vacated by the 1992 court decision (see introductory text). NIOSH kept the limits developed in the 1988 effort.

Table 10: Trichloroethylene (TCE)

	ATSDR	CalEPA	EPA	NIOSH	OSHA
Assessment date	2013	2000	2011	1988	1989
Number of reference values developed	1	1	1	2	2
First reference value (mg/m^3)	0.002 mg/m^3 (Chronic: 365 days and longer)	0.6 mg/m^3 (Chronic)	0.002 mg/m^3 (Chronic)	134 mg/m^3 (10-hour TWA, 40-hours a week for a working lifetime (all uses except as an anesthetic agent). Also noted as a carcinogen.	270 mg/m^3 (8-hour TWA)
Second reference value (mg/m^3)	-	-	-	10.7 mg/m^3 (60-minute ceiling during the use of TCE as an anesthetic agent)	1080 mg/m^3 (15-minute STEL)
Any differences in the values' uses, additional note	ATSDR adopted EPA's RfC value. Cal EPA based on a LOAEL of 11.4 ppm in Vandervort and Polnkoff (1973). See introductory text.	See introductory text.	See introductory text.	NIOSH contributed to the OSHA assessment for trichloroethylene as part of the 1988 OSHA PEL Update effort. NIOSH had assessed trichloroethylene in a 1978 criteria document and the REL of 25 ppm proposed in the PEL Update. However, OSHA promulgated a PEL of 50 ppm in the 1989 final rule.[a] See introductory text.	See introductory text.

Sources: Federal and state agency data. | GAO-14-763.

[a]The OSHA PEL for trichloroethylene is 100 ppm as an 8-hour TWA with a ceiling limit of 200 ppm and a 300 ppm 5-minute maximum peak in any 2 hours. This was changed in the 1989 PEL Update final rule to a 50 ppm TWA and a 100 ppm STEL, but were vacated by the 1992 court decision (see introductory text). NIOSH kept the limits from the 1978 criteria document. OSHA values in the 1989 final rule were 50 ppm TWA and 200 ppm STEL and the NIOSH values are 25 ppm TWA and 2 ppm ceiling only during use as an anesthetic agent.

Appendix III: GAO Contact and Staff Acknowledgments

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